IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

DEFENDANTS' FINAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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Pursuant to the Court's Order of August 28, 2020 (ECF No. 898), Defendants hereby submit their proposed findings of fact and conclusions of law. Attached hereto as Appendix A are additional proposed findings of fact regarding individual trial witnesses. Attached hereto as Appendices B through D are proposed findings of fact and conclusions of law relating specifically to AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation, respectively. Defendants incorporate those appendices by reference herein.

SUMMARY OF KEY FINDINGS AND CONCLUSIONS

1. The Court finds and concludes that Plaintiffs have failed to satisfy their burden of proving their public nuisance claim against Defendants for four principal reasons.

Public Nuisance Doctrine Inapplicable

2. The Court finds and concludes that the conduct upon which Plaintiffs' claims are predicated is not actionable under West Virginia law governing the tort of public nuisance. That conduct did not unreasonably interfere with a public right.

3. The prescription opioids that Defendants delivered to State-licensed pharmacies are approved by FDA as safe and effective for their intended use. They contain specific warning labels approved by FDA that highlight both the risks and benefits of the medicines. They are lawful products that serve an important medical purpose in treating pain.

4. The record establishes that the volume of prescription opioids Defendants delivered to pharmacies in Cabell/Huntington was driven entirely by prescriptions written by doctors. The volume of the opioid medicines Defendants delivered to pharmacies in Cabell/Huntington increased because the number of prescriptions written in good faith and in compliance with the prevailing standard of care by Cabell/Huntington doctors increased. Defendants' increased distribution of prescription opioids was therefore necessary to ensure that patients in Cabell/Huntington had access to the medicines prescribed by doctors. And under West Virginia law, conduct "which the public convenience imperatively demands cannot be a public nuisance." *Pope v. Edward M. Rude*, 75 S.E.2d 584, 589 (1953).

5. The West Virginia Supreme Court has never held that the distribution of a lawful product that subsequently causes personal injury can constitute a public nuisance. Moreover, as recognized by the Restatement (Third) of Torts, public nuisance claims based on the distribution of a product have "been rejected by most courts … because the common law of public nuisance is an inapt vehicle for addressing" that type of conduct. Restatement (Third) of Torts: Liability for Economic Harm § 8, cmt. g.

Rather, "harms caused by dangerous products are better addressed through the law of products liability." *Id.*

6. The Court finds that a public nuisance claim is not a proper vehicle for addressing the harms that flow from the use of a lawful product.

7. The Court concludes that the distribution to licensed pharmacies of FDA-approved opioid medicines used to fill prescriptions written by licensed doctors cannot constitute a public nuisance as a matter of law.

No Unreasonable Conduct

8. According to Plaintiffs, their burden was to prove unreasonable conduct on the part of each Defendant that unreasonably interfered with a public right and was a substantial factor in causing Plaintiffs' alleged harm. Plaintiffs have not proven any of that.

9. Plaintiffs did not present any evidence that any of Defendants' pharmacy customers in Cabell/Huntington was engaging in the diversion of prescription opioids—let alone that a pharmacy customer was engaging in diversion that a Defendant could or should have prevented. Absent such a showing, Plaintiffs necessarily cannot prove Defendants engaged in actionable conduct in Cabell/Huntington or that any Defendants' alleged failure appropriately to monitor the orders placed by their pharmacy customers was a substantial cause of the opioid crisis in Cabell/Huntington.

10. The only evidence in the record of pharmacy-level diversion in Cabell/Huntington related to the A-Plus Care Pharmacy in Barboursville. No Defendant supplied opioids to that pharmacy.

11. The record evidence also shows that prescription opioids were diverted to illicit use *after* they were dispensed by pharmacies to patients pursuant to prescriptions written by doctors. But, as Plaintiffs' own trial witnesses confirmed, wholesale distributors have neither the ability nor any responsibility to prevent that "medicine cabinet" diversion—which occurs outside the closed system of distribution and long after Defendants cease having any control over the medicines they deliver.

12. Rather than attempt to establish any wrongdoing that occurred in Cabell/Huntington, Plaintiffs staked their claim almost exclusively on evidence regarding the total volume of prescription opioids that Defendants shipped into Cabell/Huntington. The Court finds and concludes, however, that evidence of an increased volume of distribution, without more, is insufficient to establish a claim for public nuisance—especially where, as here, there is no evidence that Defendants shipped any more pills than were needed to fill prescriptions written by doctors in good faith and in conformity with the prevailing standard of care.

13. Plaintiffs also pointed to isolated evidence relating to Defendants' out-of-jurisdiction distributions. However, they did not present any evidence tying those distributions to diversion or harm in Cabell/County. Accordingly, the Court finds and concludes that Defendants' out-of-jurisdiction distributions are not relevant to Plaintiffs' claims.

No Causation

14. To prove causation-in-fact, Plaintiffs were required to prove that (i) had a Defendant conducted more or better due diligence regarding suspicious orders, it would have had reason to halt more orders, (ii) had it halted more orders, the orders would have gone unfilled (*i.e.*, the pharmacy customers would not have filled the orders with another distributor), and (iii) had a Defendant reported more orders as suspicious, the DEA would have taken effective enforcement action. Plaintiffs presented no such evidence—and have never argued that they did. The Court therefore finds and concludes that Plaintiffs have failed to establish causation-in-fact.

15. The Court also finds and concludes that Plaintiffs have failed to establish proximate causation.

    a. Under West Virginia law, actionable conduct "which renders a defendant liable for damages must be a proximate, ***not a remote***, cause of injury." *Metro v. Smith*, 146 W.Va. 983, 990, 124 S.E.2d 460, 464 (1962); *see also City of Charleston v. Joint Commission*, 473 F. Supp. 3d 596, 630–31 (S.D. W. Va. 2020); *Employer Teamsters Nos. 175/505 Health & Welfare Tr. Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013).

    b. *City of Charleston* is instructive. There, the court dismissed claims on proximate causation grounds, concluding that too many intervening events and the conduct of third-parties stood between the defendants' alleged conduct and the plaintiffs' alleged harm. *See City of Charleston*, 473 F. Supp. 3d at 630–31 (holding that proximate causation was absent because "numerous intervening events and parties st[ood] between" the defendants' alleged misconduct and the plaintiff municipalities' alleged injuries, including the "independent medical judgment of the prescribing physicians" and the "various criminal actions of third-parties" such as drug dealers).

    c. Just as in *City of Charleston*, the evidence at trial demonstrated that the prescription opioid medicines shipped by Defendants to DEA-registered and State-licensed pharmacies would have sat on a shelf, causing harm to no one, but for the intervening actions of numerous third parties, including (1) the doctors who wrote the prescriptions, (2) the pharmacists who dispensed the pills, (3) the patients or other actors who criminally diverted the pills, and (4) the end-users who illegally used and abused the diverted pills.

    d. Accordingly, the Court finds and concludes that "[D]efendants' actions are too attenuated and influenced by too many intervening causes" to be a proximate cause of the injuries suffered by Cabell/Huntington. *City of Charleston*, 473 F. Supp. 3d at 631.

Failure To Prove Entitlement To Abatement Remedy

16. For several reasons, Plaintiffs both failed to establish that the federal court has the power to award the requested equitable relief and failed to prove their entitlement to an abatement remedy.

17. As a threshold matter of the court's equity jurisdiction, the Court cannot award equitable relief if the plaintiff has an adequate remedy at law. As Plaintiffs have alleged, they have a legal remedy for the costs related to addiction treatment, and those costs constitute 80% or more of the requested remedy. The future costs of medical treatment for addiction are recoverable as damages, and Plaintiffs have waived any claim for damages.

18. A federal court, in the exercise of its equity jurisdiction, is also without power to award monetary relief, except when that relief is adjunct to an injunction or other forms of traditional equitable relief, such as restitution and disgorgement. Plaintiffs, however, do not seek injunctive relief, restitution, or disgorgement, and the Court is therefore without power to award purely monetary relief as "equitable" relief.

19. Even if the Court could make a purely monetary award as equitable relief, the Court would be obligated to narrowly tailor the award so as to match remedy to Defendants' wrongful conduct. *See, e.g.*, *Mayor of Baltimore v. Azar*, 973 F.3d 258, 293 (4th Cir. 2020) (quoting Swann v. Charlotte-Mecklenburg Bd. of Educ., 402 U.S. 1, 16 (1971)) ("As with any equity case, the nature of the violation determines the scope of the remedy."). Plaintiffs' proposed Abatement Plan fails to satisfy that requirement.

20. Plaintiffs' proposed remedy also must be rejected because it does not seek to "abate" the alleged nuisance (*i.e.*, the alleged "excessive" distribution of prescription opioids) but rather seeks to recover for medical treatment and other downstream harms caused by opioid abuse and addiction, which are a form of future damages and not abatement.

21. First, a very large portion of Plaintiffs' Abatement Plan is intended to address addiction that may develop in the future. But Plaintiffs have not proven any ongoing conduct by Defendants that would warrant the imposition today of liability to educate or treat people who may become addicted in the future.

22. Second, Plaintiffs admit that their Abatement Plan includes expenditures for purposes of treating people who never used prescription opioids. While that may be reasonable as a matter of social policy, there is no legal basis for Plaintiffs' suggestion that Defendants should pay for that treatment.

23. Finally, Plaintiffs' proposed Abatement Plan consists overwhelmingly of requests for funding for programs that Plaintiffs do not currently administer or pay for, and will not administer or pay for in the future. For example, the largest portion of Plaintiffs' Abatement Plan is for medical treatment of individuals with opioid use disorder, but the record is clear that the federal Medicaid program and other health insurance already pay for that treatment, and that Plaintiffs do not provide or pay for any of that treatment.

Accordingly, Plaintiffs' proposed Abatement Plan would provide them with a windfall, and for that reason is not an appropriate equitable remedy.

24. In short, the Court finds and concludes that Plaintiffs have failed to prove an entitlement to the abatement remedy they seek.

FINDINGS OF FACT

I. The Parties

1. The plaintiffs are the County Commission of Cabell County ("Cabell"), West Virginia, and the City of Huntington ("Huntington"), West Virginia (collectively, "Plaintiffs" or "Cabell/Huntington"). Third Amend. Compl. ¶¶ 26–30.

2. The defendants are AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, Inc. ("Cardinal Health"), and McKesson Corporation ("McKesson") (collectively, "Defendants").[1] Third Amend Compl. ¶¶ 127–30, 133–36, 140–43.

[1] Plaintiffs' complaint also names as defendants the following entities that were severed from this trial but remain part of the litigation before this Court and that Plaintiffs allege have caused the same injuries for which Plaintiffs seek the same relief they seek from Defendants: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Rhodes Pharmaceuticals L.P., Rhodes Technologies, Inc., Richard S. Sackler, M.D., Kathe A. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Allergan PLC f/k/a Actavis PLC f/k/a Allergan Inc., Allergan Finance LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc., Watson Laboratories, Inc., Warner Chilcott Company, LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc., Actavis Laboratories FL, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc., Teva Pharmaceutical Industries LTD., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Mallinckrodt PLC, Mallinckrodt LLC, SpecGx LLC, KVK-Tech, Inc., Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals, Inc., Impax Laboratories, LLC, Amneal Pharmaceuticals of New York LLC, CVS Health Corporation, CVS Indiana L.L.C., CVS Rx Services, Inc., CVS Tennessee Distribution, L.L.C., CVS Pharmacy, Inc., West Virginia CVS Pharmacy, LLC, Rite Aid Corporation, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., Rite Aid of West Virginia, Inc., Walgreens Boots Alliance, Inc., Walgreen Eastern Co., Inc., Walgreen Co., H.D. Smith Wholesale Drug Co., Kroger Limited Partnership I, Kroger Limited Partnership II, Walmart Inc., Wal-Mart Stores East d/b/a Wal-Mart Pharmacy Warehouse #46, Wal-Mart Pharmacy Warehouse #45, Wal-Mart Pharmacy Warehouse, Express Scripts Holding Company, Express Scripts, Inc., Caremark Rx, LLC, Optum, Inc., OptumRx Inc., and Tasmanian Alkaloids Pty. LTD. *See* Third Amend. Compl. ¶¶ 42–123, 146–299.

3. Defendants are wholesale distributors of medical products and supplies and distribute a full line of medical products and supplies to pharmacies and hospitals across the country, including prescription and over-the-counter medicines. *See* 5/13 Tr. (Zimmerman) at 149:3–14, 149:23–150:2; 5/20 Tr. (Moné) at 175:1–10; 5/25 Tr. (Oriente) at 7:21–8:5, 10:19–25.

4. Defendants are now, and at all relevant times have been, registered with the U.S. Drug Enforcement Administration ("DEA") and licensed by the West Virginia Board of Pharmacy to engage in the wholesale distribution of controlled substances.

   a. Plaintiffs offered no evidence that Defendants ever operated without proper licenses and registrations.

   b. Mr. Zimmerman testified that AmerisourceBergen was at all times registered with DEA and licensed by the West Virginia Board of Pharmacy, including its Lockbourne Distribution Center, which was responsible for distributing into West Virginia and Cabell County. *See* 5/13 Tr. (Zimmerman) at 152:20–153:5, 171:3–17.

   c. Mr. Moné testified that Cardinal Health's Wheeling, West Virginia distribution center was continuously registered by DEA. *See* 5/20 Tr. (Moné) at 193:20–194:9.

   d. Mr. Oriente testified that McKesson's distribution centers responsible for shipping controlled substances into the State of West Virginia are licensed by the West Virginia Board of Pharmacy. *See* 5/25 Tr. (Oriente) at 15:15–16:24; Ex. MC-WV-02149 (compilation of McKesson's West Virginia licenses). Mr. Oriente further testified that each of McKesson's distribution centers is individually registered by DEA, and is renewed every year. *See* 5/25 Tr. (Oriente) at 13:1–19.

5. Defendants purchase medical supplies and prescription medicines from manufacturers and distribute them to pharmacies, hospitals, and other licensed dispensers. *See* 5/13 Tr. (Zimmerman) at 149:7-14; 5/20 Tr. (Moné) at 178:12–16; 5/25 Tr. (Oriente) at 7:21–8:5; 5/26 Tr. (Rafalski) at 148:12–16; 6/16 Tr. (Yingling) at 173:11–20; 7/8 Tr. (Murphy) at 64:20–65:13.

6. Defendants ship controlled substances only in response to pharmacy[2] orders; they do not distribute directly to doctors or patients.

   a. Plaintiffs presented no evidence of prescription opioid shipments by Defendants that were shipped to a pharmacy without an order placed by the pharmacy for that shipment. *See* 5/12 Tr. (McCann) at 65:19–23; 6/30 Tr. (Williams) at 78:20–79:3.

   b. Plaintiffs presented no evidence that any prescription opioids distributed by Defendants were dispensed to patients by anyone other than pharmacists who had

[2] As used herein, "pharmacy" or "pharmacist" refers to licensed dispensers generally.

corresponding responsibilities to ensure the legitimacy of the prescriptions. *See* 5/26 Tr. (Rafalski) at 132:24–133:4.

c. The number of prescriptions written by doctors drives the quantity of prescription opioids sold in the marketplace, and the amount of controlled pharmaceuticals shipped by distributors is determined by doctors' prescriptions, because pharmacies order prescription opioids based on anticipated volume of prescriptions. *See* 7/8 Tr. (Murphy) at 66:22–67:4, 74:3–18, 64:20–65:13, 68:19–69:9.

d. When doctors write more prescriptions for a medication, pharmacies necessarily order more of that medication from distributors. *See* 5/4 Tr. (Waller) at 91:21–92:1.

7. Defendants play an essential role in distributing prescription opioids and other medicines to pharmacies, hospitals, and other licensed dispensers so that they are available to patients on a timely basis, including to patients in West Virginia and Cabell/Huntington.

a. Distributors' role is to fill orders from pharmacies so that pharmacies have medications on hand to dispense when they are presented with prescriptions. *See* 5/4 Tr. (Waller) at 91:13–20.

b. Mr. Rannazzisi testified that "it's vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care," and that it is a "public health concern when pharmacies cannot dispense legitimate pharmaceutical controlled substances to patients." *See* 6/9 Tr. (Rannazzisi) at 87:12–19. Mr. Rannazzisi further testified that "distributors play an important role in [e]nsuring an adequate and uninterrupted supply of prescription opioids" and that "if a patient doesn't get the medication they need, there's a breakdown in the system." *See id.* at 155:8–19.

c. Mr. Rafalski testified that "distributors play an important role in ensuring an adequate and uninterrupted supply of legitimate prescription opioids." *See* 5/26 Tr. (Rafalski) at 148:17–21.

d. Distributors play an important role in ensuring "just in time delivery," whereby they provide daily ordering services to licensed dispensers. *See* 5/17 Tr. (May) at 33:11–34:15.

e. Distributors have an important mission because they ensure availability of "lifesaving drugs" and "maintenance drugs that people need in order to live day-to-day." *See* 5/25 Tr. (Oriente) at 8:9–12.

8. Defendants do not prescribe opioid medicines or any other pharmaceutical products; prescribing is done by doctors.[3]

   a. Dr. Waller testified that the decision whether to prescribe opioid medicines and what dosage to prescribe is made by doctors in collaboration with their patients. *See* 5/4 Tr. (Waller) at 88:13–89:4.

   b. Dr. Gupta testified that the decision to use opioids for chronic pain treatment should be entrusted to a licensed doctor acting in concert with the patient. *See* 5/5 Tr. (Gupta) at 188:24–189:1; 5/6 Tr. (Gupta) at 46:10–15, 68:7–11, 68:25–69:8, 76:20–77:10.

   c. Mr. Rafalski testified that doctors and other prescribers are responsible for determining medical need when they write prescriptions for opioids, and are supposed to write prescriptions for opioids only if they have a doctor/patient relationship and make a judgment that a patient has a legitimate medical need for those opioids. *See* 5/26 Tr. (Rafalski) at 116:15–24.

   d. Dr. Smith testified that a prescribing physician is in the best position to evaluate the risks and benefits, including the risk of addiction, of prescribing any specific drug to a patient. *See* 6/10 Tr. (Smith) at 162:12–20.

   e. Dr. Keyes testified that doctors decide on the dosage strength and number of pills to include in a given prescription. *See* 6/14 Tr. (Keyes) at 70:11–16, 88:19–23.

   f. Mayor Williams testified that it is up to a physician to decide who has a legitimate need for prescription opioids. *See* 6/30 Tr. (Williams) at 81:25–82:4.

   g. Dr. Werthammer testified that wholesale distributors do not prescribe medicines. *See* 5/21 Tr. (Werthammer) at 22:14–16.

   h. Dr. Gilligan testified that doctors are charged with making the judgment about when and by whom prescription opioids should be used, and that doctors are best situated to make those decisions because they possess patient information, training and expertise, and the responsibility and authority to make such decisions. *See* 7/2 Tr. (Gilligan), at 9:6–13, 72:1–25. Dr. Gilligan further testified that no one in the healthcare system knows the patient better than his or her doctor or clinician. *See id.* at 73:4–17.

   i. Dr. Murphy testified that a legal prescription is required before a prescription opioid can be sold in the marketplace, and that doctors are responsible for writing opioid prescriptions. *See* 7/8 Tr. (Murphy) at 67:5–68:3.

[3] As used herein, the word "doctors" refers both to physicians and other licensed prescribers.

j. Mr. Cox testified by deposition designation[4] that doctors are responsible for deciding, and are in the best position to decide, whether prescription opioids are medically appropriate for the treatment of chronic pain. *See* D. Cox 7/15/20 Dep. Designations at 35:10–19, 36:12–13.

9. Defendants do not interact with patients, do not have access to patients' medical histories (individually or in the aggregate), and have no ability or authority to second-guess a medical professional's judgment to prescribe any particular medicine for any particular patient, including prescription opioid medicines.

a. Dr. Waller testified that distributors do not play any role in deciding whether to prescribe opioids and do not interact with patients. *See* 5/4 Tr. (Waller) at 87:21–89:4, 90:19–21. Dr. Waller further testified that distributors do not determine whether a patient is authorized to refill a prescription. *See id.* at 90:8–14.

b. Mr. Rafalski testified that Defendants do not check prescriptions, do not have access to individual patient prescriptions or individual patient data, and therefore "don't have the information to evaluate the medical need of an individual patient presenting an individual prescription." *See* 5/26 Tr. (Rafalski) at 148:25–149:13. Mr. Rafalski further testified that DEA "does not expect distributors to second-guess the legitimate medical judgments of prescribers." *See id.* at 117:8–12.

c. Mr. Rannazzisi testified that Defendants "don't have access to individual patient records because of privacy laws" and "can't second-guess legitimate medical decisions by prescribers." *See* 6/9 Tr. (Rannazzisi) at 154:14–155:2. Mr. Rannazzisi further testified that "a distributor cannot make the determination if a controlled substance is medically necessary for a particular patient," and testified that DEA has "never asked a distributor to do that." *See id.* at 98:16–19. Mr. Rannazzisi further testified that DEA "never required [distributors] to look at what doctors were doing," or "question[] … a doctor's prescribing habits." *See* 6/8 Tr. (Rannazzisi) at 186:15–17.

d. Dr. Yingling testified that distributors do not interact with doctors related to the care and treatment of individual patients, and have never influenced his own prescribing practices. *See* 6/16 Tr. (Yingling) at 188:2–8.

e. Dr. Smith testified that distributors have nothing to do with individual patients and could not evaluate individual risks of addiction. *See* 6/10 Tr. (Smith) at 162:21–163:2.

f. Dr. Gilligan testified that distributors do not play a role in deciding whether doctors prescribe opioids or other medicines, and do not play a role in determining the level of opioids doctors prescribe. *See* 7/2 Tr. (Gilligan), at 9:14–20. Dr. Gilligan further testified that distributors do not influence how doctors prescribe opioids and do not

[4] The parties' respective deposition designations (and corresponding exhibits) remain pending before the Court and have not yet been formally admitted.

play a role in determining how many prescriptions for opioids are written in a given point in time. *See id.* at 146:22–147:3, 147:9–14. Dr. Gilligan also testified that it would not be helpful for patients or for society for distributors or others to second-guess the judgments of doctors. *See id.* at 74:2–10.

g. Dr. Murphy testified that distributors do not decide whether to ship opioids to fill any individual prescription or whether an individual prescription is likely to be used legitimately or diverted in some way. *See* 7/8 Tr. (Murphy) at 68:4–18.

h. Mr. Zimmerman testified that AmerisourceBergen does not interact with patients, consult with doctors on prescribing decisions, or make medical decisions. *See* 5/13 Tr. (Zimmerman) at 155:12–20, 157:14–158:8. Mr. May also testified that AmerisourceBergen does not interact with patients, does not see the diagnosis of a patient that the prescriber made, and has no role in or insight into the patient/doctor relationship. *See* 5/17 Tr. (May) at 126:8-19.

i. Mr. Moné testified that Cardinal Health has "no relationship to the patient." *See* 5/20 Tr. (Moné) at 178:16–18. Mr. Reardon and Mr. Brantley testified by designation that Cardinal Health does not interact directly with patients or with doctors. *See* S. Reardon 11/30/2018 Dep. Designations at 499:20–24; E. Brantley 11/27/2018 Dep. Designations at 520:1–6.

j. Mr. Oriente testified that McKesson does not "talk[] with prescribers … about the medicines they're prescribing" or "interact directly with patients in terms of talking with them about what medicines they should use." *See* 5/25 Tr. (Oriente) at 30:13–22.

10. Defendants do not dispense prescription opioids to patients; dispensing is done by licensed pharmacies and other licensed dispensers. *See* 5/4 Tr. (Waller) at 91:18–20; 5/26 Tr. (Rafalski) at 148:22–24.

11. Defendants do not manufacture prescription opioids; manufacturing is done by pharmaceutical manufacturers. *See* 5/25 Tr. (Oriente) at 22:1–9; 5/26 Tr. (Rafalski) at 137:22–24; 5/13 Tr. (Zimmerman) at 150:14-16.

12. Defendants do not develop prescription opioids or seek approval from the Food and Drug Administration ("FDA") to market them. *See* 5/26 Tr. (Rafalski) at 138:5–10; 6/11 Tr. (Mohr) at 116:2–12.

13. Defendants do not develop or conduct clinical tests or scientific studies on the risks and benefits of prescription opioids or other medicines.

a. Mr. Rafalski testified that manufacturers are charged with studying prescription opioids before and after FDA-approval. *See* 5/26 Tr. (Rafalski) at 137:25–138:4.

b. Dr. Keyes testified that pharmaceutical manufacturers were the ones who applied to FDA for approval of prescription opioid medications based on representations about the risks and benefits of those drugs. *See* 6/14 Tr. (Keyes) at 51:23–52:2.

c. Dr. Mohr testified that manufacturers are responsible for making representations to FDA about the risks and benefits of opioids for purposes of developing the product label, and testified that distributors do not develop the labeling statements about the risks and efficacy of particular prescription opioids. *See* 6/11 Tr. (Mohr) at 116:2–12, 116:23–117:1.

d. Dr. Gilligan testified that manufacturers of medications are responsible for the contents of FDA-approved product labels, and that distributors do not have a role in the substance of medication labeling. *See* 7/2 Tr. (Gilligan) at 44:4–10, 44:25–5, 95:17–20.

14. Defendants do not determine the total number of prescription opioids that may lawfully be manufactured and distributed within the United States; that is done by DEA each year based on its assessment of the legitimate medical and scientific need for those medicines. *See* 21 U.S.C. § 826; *see also infra* Findings ¶¶ 71–75.

15. Between 2006 and 2014, more than 30 companies other than Defendants distributed prescription opioids in Cabell/Huntington. *See* 5/11 Tr. (McCann) at 153:9–24, 154:22–155:2, 155:15–25.

II. Changes in the Standard of Care for the Treatment of Pain and in the Use of Prescription Opioids for the Treatment of Pain

16. The "standard of care" is what reasonable doctors would adhere to within their field of medicine in a given situation. *See* 7/7 Tr. (Deer) at 48:14–19; *see also* 7/2 Tr. (Gilligan) at 76:5–15 (testifying that the standard of care is the quality of care, thoughtfulness, and safety that doctors are expected to maintain in a given field).

17. The standard of care changes over time based on research, development, and new information. *See* 7/7 Tr. (Deer) at 34:11–17.

18. Doctors prescribe medications based on the then-prevailing standard of care, and doctors who do not follow the then-prevailing standard of care can lose their license or face civil or criminal consequences. *See* 7/7 Tr. (Deer) at 49:17–50:19.

19. Chronic pain is a common, debilitating medical condition that can have a severe impact on patients. Accordingly, pain management is an integral component of good medical practice.

a. Dr. Keyes testified that chronic pain is a debilitating medical condition. *See* 6/14 Tr. (Keyes) at 111:17–20.

b. Dr. Waller testified that pain management is integral to good medical practice for all patients. *See* 5/4 Tr. (Waller) at 164:4–9.

c. Dr. Gilligan testified that physicians should prescribe opioids when necessary as an exercise of their moral and ethical obligations to treat pain. *See* 7/2 Tr. (Gilligan)

at 34:24–35:10; *see also* Ex. MC-WV-01170 (Institute of Medicine Report) at .00047.

d. Dr. Deer testified that pain can have a cascading effect that impacts patients' family life and ability to make a living. *See* 7/7 Tr. (Deer) at 14:4–15:1.

20. Prescription opioids are medicines approved by FDA as safe and effective for the treatment of pain, including for acute pain following injury or surgery, for cancer pain, for easing pain through palliative care at the end of life, and for chronic pain in appropriate circumstances.

a. Dr. Waller testified that FDA-approved prescription opioids have legitimate medical uses, and can be effective for treatment of acute pain and palliative care. *See* 5/4 Tr. (Waller) at 80:16–81:9, 85:3–23. Dr. Waller further testified that prescription opioids can be appropriate for treatment of chronic pain as a drug of last resort. *See id.* at 87:5–8.

b. Ms. Priddy testified that prescription opioids have medically appropriate uses, and can be legitimately prescribed by physicians, administered by nurses, and dispensed by pharmacies. *See* 5/6 Tr. (Priddy) at 215:12–20. Ms. Priddy further testified that opioids are indicated for use in many emergency situations, and that West Virginia requires all EMS ambulances in the state to carry opioid medications and to use morphine and medical fentanyl during certain emergency situations. *See id.* at 215:21–23, 218:15–21, 220:1–19, 222:4–8.

c. Dr. Werthammer testified that prescription opioids are approved by FDA. *See* 5/21 Tr. (Werthammer) at 35:8–10.

d. Dr. Keyes testified that prescription opioids are approved by FDA. *See* 6/14 Tr. (Keyes) at 51:14–17. Dr. Keyes further testified that opioids relieve pain, and that there are circumstances in which an opioid would be an appropriate medical treatment. *See id.* at 13:17–25. In 2013, Dr. Keyes published a paper that stated "[w]hen used as prescribed under medical supervision, opioid analgesics are effective and used as standard practice in managing acute and chronic pain." *See id.* at 15:6–18, 17:3–8. Dr. Keyes believed that statement was true based on the literature she had reviewed at the time. *See id.* at 17:3–8.

e. Dr. Yingling testified that there are patients for whom prescription opioid medication is necessary medical care. *See* 6/16 Tr. (Yingling) at 218:12–14.

f. Dr. McGuire testified that FDA, in approving prescription opioids, determined that prescription opioids offer benefits to certain populations. *See* 6/17 Tr. (McGuire) at 35:20–25.

g. Dr. Gilligan testified that it is the consensus of the medical community that the benefits of prescription opioids outweigh the risks for certain patients, and that is reflected in the fact that prescription opioids are FDA-approved. *See* 7/2 Tr.

(Gilligan) at 38:6–12, 39:5–16. Dr. Gilligan further testified that opioids play a central role in the treatment of chronic cancer pain. *See id.* at 32:2–12.

h. Dr. Gilligan testified that prescription opioids are the most potent pain medications, and that certain patients with severe, disabling pain cannot be treated successfully or safely with non-opioid treatments. *See* 7/2 Tr. (Gilligan) at 66:23–67:14. Although studies on the efficacy of prescription opioids for chronic pain are mixed, they are safe and effective for the treatment of chronic pain for certain patients. *See id.* at 69:13–70:8.

i. Dr. Deer testified that prescribing opioids is appropriate for the correct patient. *See* 7/7 Tr. (Deer) at 37:18–20.

j. Mayor Williams testified that opioids serve a legitimate purpose for treating people who are in pain. *See* 6/30 Tr. (Williams) at 82:8–10.

k. Mr. Prevoznik testified by deposition designation that DEA agrees there is a legitimate medical need under 21 U.S.C. § 801 for prescription opioids to treat pain. *See* T. Prevoznik 4/17/19 Dep. Designations at 393:10–14, 393:17–18. Mr. Prevoznik further testified that DEA agrees that opioids are an appropriate medication for many Americans, and that prescription opioids are necessary to maintain the general welfare of American people who need them. *See id.* at 392:23–393:3, 393:8, 394:8–12.

21. For most of the 20th century, medical professionals prescribed opioid pain medicines only for acute and cancer pain. *See, e.g.*, Ex. MC-WV-02079 (Compton 2019) at .00005 (stating that before the 1980s, physicians and other healthcare providers were "reluctant to use [opioid drugs] to treat most pain conditions"); 6/16 Tr. (Yingling) at 176:4–6 (agreeing that "[u]p until the 1990s, prescription opioids were primarily used for acute pain and cancer pain."); 7/7 Tr. (Deer) at 68:5–13 (testifying that doctors did not regularly prescribe opioids for chronic non-malignant pain prior to 1997).

22. Beginning in the 1980s, there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain.

a. Dr. Waller testified that the undertreatment of pain has been recognized as a public health crisis for decades. *See* 5/4 Tr. (Waller) at 163:9–19. Dr. Waller further agreed with the statement that "[b]eginning in the 1980s … there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain, both in cancer and palliative care patients, and even more generally." *See id.* at 172:7–16; *see also* Ex. MC-WV-02079 (Compton 2019) at .00005.

b. Dr. Gilligan testified that in the 1980s and 1990s, there was emphasis on the ideas that doctors were under-treating pain, exaggerating the risks of opioids, and ultimately under-utilizing them as a result. *See* 7/2 Tr. (Gilligan) at 76:22–77:4.

c. Dr. Yingling testified that, during the 1990s, he came to believe that pain was undertreated. *See* 6/16 Tr. (Yingling) at 177:20–178:6.

d. In a 1982 article titled published in the New England Journal of Medicine, Dr. Marcia Angell stated that pain treatment was "regularly and systematically inadequate," that "most pain, no matter how severe, can be effectively relieved by narcotic analgesics," that "a more important factor is a disproportionate sometimes irrational fear on the part of the medical profession and the public alike that patients will become addicted," and that "[p]ain is soul destroying." *See* Ex. MC-WV-01135 (1982 Angell Article) at .00002–.00003; *see also* 7/2 Tr. (Gilligan) at 78:14–79:17, 82:11–88:7.

e. In 1986, the World Health Organization released a document called "Cancer Pain Relief" that said opioids were "under-use[d]" and introduced a highly influential pain ladder that called for progression toward more powerful opioids as pain became more severe. It also said that "[a]n analysis of 11 reports covering nearly 2000 patients in developed countries suggests that 50–80% of patients did not have satisfactory [pain] relief." *See* Ex. DEF-WV-03699 (1986 WHO Document) at .00010, .00015, .00020–.00021; *see also* 7/2 Tr. (Gilligan) at 88:8–89:4, 89:25–94:22.

f. A 2007 book by Dr. Scott Fishman titled *Responsible Opioid Prescribing* stated that "[t]here is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades." *See* Ex. MC-WV-02111 (*Responsible Opioid Prescribing*) at 111; *see also* 5/4 Tr. (Waller) at 163:9–19.

g. In 2008, the West Virginia Board of Medicine distributed a copy of *Responsible Opioid Prescribing* to every doctor in West Virginia. *See* Ex. DEF-WV-03616 (2008 West Virginia Board of Medicine Newsletter) at .00006; 7/7 Tr. (Deer) at 102:10–19.

23. Beginning in the 1990s, the standard of care changed to recognize a broader range of appropriate uses for prescription opioids nationwide, including for the long-term treatment of chronic non-cancer pain.

a. Dr. Waller testified that there was a "sea change" in opioid medication prescribing that began in the mid-1990s and "hit its peak between 2010 and 2012." *See* 5/4 Tr. (Waller) at 94:9–20. Dr. Waller further testified that it was through pain suffering and the shifting philosophies of pain treatment that today's opioid crises first took root. *See id.* at 171:9–172:6.

b. Dr. Gilligan testified that the standard of care of the use of prescription opioids has changed over the past several decades. *See* 7/2 Tr. (Gilligan) at 76:16–19.

c. Dr. Deer testified that the standard of care for the use of prescription opioids has changed over time, and that this change has affected the rate at which doctors prescribed opioids in West Virginia. *See* 7/7 Tr. (Deer) at 129:3–13. Dr. Deer further testified that there were "three main phases" of the standard of care in West Virginia. *See id.* at 39:17–23.

d. A 2019 article published by Dr. Wilson Compton—Deputy Director of the National Institute on Drug Abuse (or, "NIDA")—explained how an emphasis on the treatment of pain beginning in the 1980s led to increased prescribing of prescription opioids in the 1990s for a broader set of conditions, including chronic non-cancer pain. *See* Ex. MC-WV-02079 (Compton 2019) at .00005–.00006.

e. Plaintiffs alleged in their Complaint that, beginning in the 1990s, the manufacturers of prescription opioids "design[ed] and implement[ed] a sophisticated and deceptive market strategy" "to change prescriber habits and public perception and increase demands for opioids." *See* Appendix A on Trial Mem. Regarding Admissibility of Pls.' Judicial Admission Concerning Manufacturer Conduct (ECF No. 1462–1). Plaintiffs alleged that the marketing campaign was extremely successful and "by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions." Third Amend. Compl. ¶¶ 375–76. These allegations are judicial admissions. *See* ECF Nos. 1462, 1484.

24. The change in the standard of care was reflected in the widespread adoption of "Pain as the Fifth Vital Sign," a concept that encouraged doctors and other healthcare professionals to both (1) monitor patient pain as closely as other vital signs and (2) address patient pain more aggressively. "Pain as the Fifth Vital Sign" was promoted by third-party organizations like the Joint Commission on Accreditation of Healthcare Organizations ("Joint Commission").

a. Dr. Waller testified that "Pain as the Fifth Vital Sign" referred to the practice of monitoring patient pain as closely as other vital signs like blood pressure and respiration. The practice also embraced addressing pain more aggressively. *See* 5/4 Tr. (Waller) at 96:1–8. Dr. Waller further testified that "Pain as the Fifth Vital Sign" had an effect on the prescribing of opioids by some doctors. *See id.* at 97:10–16.

b. Dr. Waller testified that the concept of "Pain as the Fifth Vital Sign" originated with the Joint Commission, which is the regulatory body that the government uses to identify and evaluate hospitals for safety. *See* 5/4 Tr. (Waller) at 96:9–12, 96:17–21. A hospital may participate in federal healthcare programs like Medicaid and Medicare only if it is accredited by the Joint Commission. *See id.* at 96:22–97:1. Dr. Waller testified that, in the early-to-mid 2000s, the Joint Commission made implementing "Pain as the Fifth Vital Sign" a criteria for accreditation, and that doctors practicing in a hospital accredited by the Joint Commission had to comply with these standards. *See id.* at 97:2–9.

c. Dr. Keyes published an article in April 2021 stating that one of the two forces that led to the proliferation of opioid prescribing in the 1990s "was a shift in treatment approaches for chronic non-cancer pain, including a campaign by professional pain societies and the U.S. Joint Commission, the nation's largest accrediting body for healthcare organizations, to consider pain as the fifth vital sign and to improve the quality of care for chronic pain." *See* 6/14 Tr. (Keyes) at 34:9–19. Dr. Keyes

testified that the Joint Commission's endorsement of "Pain as the Fifth Vital Sign" contributed to increases in opioid use disorder in West Virginia. *See id.* at 49:9–15.

d. Ms. Priddy testified that "Pain as the Fifth Vital Sign" involved putting pain on the same level of importance as a patient's temperature or respiration, and that under "Pain as the Fifth Vital Sign," if a patient indicated pain, the attending medical professional needed to address the patient's pain. *See* 5/6 Tr. (Priddy) at 217:19–218:6.

e. Dr. Werthammer testified that "Pain as a Fifth Vital Sign" came from organizations like the Joint Commission, and that opioids were prescribed more liberally at the time when pain was considered the "fifth vital sign." *See* 5/21 Tr. (Werthammer) at 27:3–6, 27:13–16. In a February 2016 e-mail thread discussing the opioid crisis, Dr. Werthammer wrote "it was not big pharma who wrote the prescriptions, it was me and my colleagues." See Ex. DEF-WV-00473. Dr. Shapiro responded, "We had some help. Pain as the '5th vital sign' comes to mind …." *Id.*

f. Dr. Yingling testified that the American Pain Society designated "Pain as the Fifth Vital Sign" in 1995, and that the Joint Commission mandated hospitals ask their patients about pain and treat that pain beginning in 2001. *See* 6/16 Tr. (Yingling) at 179:18–23, 180:4–19. Dr. Yingling further testified that the designation of pain as the fifth vital sign had the effect of increasing net prescribing of pain medications. *See id.* at 182:16–20.

g. Dr. Feinberg testified that she observed the concept of "Pain as the Fifth Vital Sign" being promoted by institutions such as the Joint Commission, and that doctors practicing in the hospital setting or in other organizations that adopted the concept "would have felt pressure to abide by those new regulations or new recommendations." *See* 6/17 Tr. (Feinberg) 168:7–169:10.

h. Dr. Gilligan testified that, in 2001, the Joint Commission released pain standards that included measuring pain as a fifth vital sign. Vital signs, like heart rate and blood pressure, are very important, and adding pain as a fifth vital sign was a clear reflection of the importance the Joint Commission placed on the measurement of pain. *See* 7/2 Tr. (Gilligan) at 106:7–107:12. Dr. Gilligan further testified that it is very important for hospitals to maintain their accreditation with the Joint Commission, and therefore the Joint Commission's 2001 Pain Standards were extremely influential in the practice of medicine. *See id.* at 106:7–107:12, 110:8–16.

i. The Joint Commission's 2001 Pain Standards emphasized the importance of treating pain, and provided examples for implementing its standards that included asking every patient "a 'screening' question regarding pain on admission" and posting a "statement on pain management … in all patient care areas" stating that "[a]ll patients have a right to pain relief." *See* Ex. AM-WV-02693 (Joint Commission 2001 Pain Standards); *see also* 7/2 Tr. (Gilligan) at 105:15–112:22.

j. Dr. Deer testified that "Pain as the Fifth Vital Sign" became an important factor because every patient that walked into a hospital, inpatient or outpatient, had to be asked about their pain level, and that pain level had to be followed and addressed throughout their care. *See* 7/7 Tr. (Deer) at 53:12–23. Dr. Deer further testified that "Pain as the Fifth Vital Sign" was promoted by the American Pain Society and the Joint Commission, among others, and that "Pain as the Fifth Vital Sign" contributed to the change in the standard of care towards more opioid prescribing. *See id.* at 53:24–54:3, 57:3–8, 60:3–10, 60:20–61:1, 61:23–62:1; *see also* Ex. DEF-WV-02395 (American Pain Society), Ex. DEF-WV-03074 (VA Pain as the Fifth Vital Sign Toolkit). Dr. Deer was not aware of any distributor role in the Joint Commission or VA documents on Pain as the Fifth Vital Sign. *See id.* at 63:20–24.

k. Dr. Compton's 2019 article stated that "in the early 1990s, advocacy groups, including the American Pain Society, encouraged physicians to treat pain as a 'fifth vital sign,' and the Joint Commission began to require hospitals to assess all patients' pain." *See* Ex. MC-WV-02079 (Compton 2019) at .00006. As a result, "[p]ain rating scales became ubiquitous in doctor's offices and emergency rooms," leading to "a marked increase in opioid prescribing and subsequent public health harms." *See id.*

l. A separate lawsuit filed by the City of Huntington against the Joint Commission alleged that the Joint Commission played a key role in the concept of "Pain as the Fifth Vital Sign," which led to increasing prescribing of pain medications. *See* Ex. DEF-WV-01102 (2017 City of Huntington Press Release); Ex. DEF-WV-02124 (Joint Commission Complaint); *see also* 6/30 Tr. (Williams) at 92:20–103:5. In particular, Huntington alleged that:

    a. the Joint Commission "teamed with Purdue Pharma L.P. … as well as other opioid manufacturers, to issue Pain Management Standards … and other related documents that grossly misrepresented the addictive qualities of opioids and fostered dangerous pain control practices, the result of which was often the inappropriate provision of opioids," *see* Ex. DEF-WV-02124 (Joint Commission Complaint) ¶ 1;

    b. "Hospitals ... were required to follow these Pain Management Standards to maintain [Joint Commission] certification, which health care organizations deem essential to their continued operation," *see id.* ¶ 3; and

    c. the Joint Commission's "enforcement of its Pain Management Standards and … widespread misinformation campaign about the safety of opioids has also led to an overprescribing of opioids, not only in terms of doses and necessity, but also in terms of quantity," *see id.* ¶ 8.

m. Mayor Williams endorsed and agreed with the City's allegations against the Joint Commission, and testified that that the Joint Commission is "one of the most

culpable parties responsible for the opioid problem." *See* 6/30 Tr. (Williams) at 92:20–103:5.

25. Plaintiffs also allege and therefore admit[5] that the change in the standard of care was influenced by a deceptive advertising campaign by the manufacturers of prescription opioids, which generally overstated the benefits and understated the risks of opioid treatment.

a. Plaintiffs judicially admit that a deceptive advertising campaign by the manufacturers of prescription opioids played a role in changing the standard of care. *See* Third Amend. Compl. ¶¶ 372–76.

b. Plaintiffs judicially admit that manufacturers made nine false or misleading marketing claims about prescription opioids. *See* Third Amend. Compl. ¶¶ 378, 384–537. Plaintiffs presented no evidence that Distributors made any of these claims.

c. Plaintiffs judicially admit that manufacturers disseminated their false or misleading marketing claims through eight different channels. *See* Third Amend. Compl. ¶¶ 539–650. Plaintiffs presented no evidence that Distributors used any of these channels.

d. Dr. Waller testified that marketing outreach to primary care physicians was done by manufacturers. *See* 5/4 Tr. (Waller) at 219:2–5. Dr. Waller further testified that the manufacturers' marketing of OxyContin included high levels of targeted outreach to primary care physicians, outreach at national meetings, incentivized sales, and even illegal sales practices, all of which fueled the multi-billion-dollar medication sales increase starting in the 1990s. Dr. Waller further testified that these practices found a particular niche in some rural areas where limited access to integrated pain treatment and high prevalence of pain conditions facilitated proliferation of prescription opioids and misuse. *See id.* at 199:22–201:2.

e. Dr. Mohr testified that manufacturers, not distributors, engage in physician detailing, and maintain large sales detailing forces to consistently call on doctors and make representations about the risks and benefits of prescription opioids. *See* 6/11 Tr. (Mohr) at 122:3–123:1, 123:11–21. Dr. Mohr further testified that manufacturers detail physicians for the purpose of expanding sales of their products. *See id.* at 123:6–10.

[5] Under the rule of judicial admission, "a party is bound by the admissions of his pleadings." *Lucas v. Burnley*, 879 F.2d 1240, 1242 (4th Cir. 1989); *see also Butts v. Prince William Cnty. Sch. Bd.*, 844 F.3d 424, 432 n.3 (4th Cir. 2016) (same). Thus, it is well-established that the factual allegations in a complaint constitute binding judicial admissions by the plaintiff that made them. *See generally* Defs.' Trial Mem. Regarding Admissibility of Pls.' Judicial Admissions Concerning Manufacturer Conduct (ECF No. 1462) & Appendix A.

f. Dr. Werthammer testified that manufacturers of prescription opioids, like Purdue, detailed doctors about the benefits of prescription opioids. 5/21 Tr. (Werthammer), at 30:8–25. Dr. Werthammer further testified that manufacturer marketing about the addiction potential of prescription opioids had the effect of increasing doctors' prescribing of opioids. *See id*.

g. Mr. Rafalski agreed with the GAO's conclusion that "Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force and multiple promotional approaches to encourage physicians, including primary care specialists, to prescribe OxyContin as an initial opioid treatment for noncancer pain." 5/26 Tr. (Rafalski) at 141:18–142:4; *see also* Ex. MC-WV-01764 (GAO Report) at .00009. Mr. Rafalski further agreed with the GAO's conclusion that "DEA has expressed concern that Purdue's aggressive marketing of OxyContin focused on promoting the drugs to treat a wide range of conditions to physicians who may not have been adequately trained in pain management." *See* 5/26 Tr. (Rafalski) at 142:10–17; *see also* Ex. MC-WV-01764 (GAO Report) .00009.

h. Dr. Keyes published an article in April 2021 stating that the second force that led to the proliferation of opioid prescribing in the 1990s "involved the pharmaceutical industry's concerted efforts to advocate for the long-term use of opioids as a safe, non-addictive, effective, and humane alternative to treat non-cancer pain," including "Purdue Pharma provid[ing] funds for educational campaigns supporting the use of opioids to treat chronic non-cancer pain." 6/14 Tr. (Keyes) at 34:20–35:12.

i. Mayor Williams agreed with Plaintiffs' allegations that manufacturers' marketing, including the actions of Purdue Pharma, caused prescribing of opioids to increase in Cabell/Huntington. *See* 6/30 Tr. (Williams) at 85:9–21, 86:3–87:7, 87:25–88:6.

j. Mr. Knittle testified by deposition designation that pharmaceutical manufacturers promoted the idea that opioids were the first and foremost pain treatment. *See* R. Knittle 8/27/20 Dep. Designations at 101:24–102:13.

26. The Federation of State Medical Boards ("FSMB") and professional societies promulgated guidelines that approved this new standard of care.

a. The FSMB is an umbrella organization for state medical boards, including the West Virginia Board of Medicine. *See* 5/4 Tr. (Waller) at 107:16–24.

b. In 1998, the FSMB released "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." *See generally* Ex. DEF-WV-02937 (FSMB 1998 Guidelines). The 1998 FSMB Guidelines stated, among other things, that "opioid analgesics[] may be essential in the treatment of acute pain due to trauma or surgery and chronic pain whether due to cancer or non-cancer origins," and that "[p]hysicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction." *See id.* at .00001; *see also* 7/2 Tr. (Gilligan) at 101:10–104:24.

c. Plaintiffs alleged, and therefore admit, that the FSMB Guidelines approved the long-term use of opioids to treat chronic pain. *See, e.g.*, Third Amend. Compl. ¶ 567.

d. The FSMB's 1998 guidelines were endorsed by various organizations, including state medical boards, medical professional organizations, healthcare regulatory boards, and DEA. *See* 7/2 Tr. (Gilligan) at 119:17–120:11; *see also* Ex. DEF-WV-03605 (FSMB 2004 Guidelines) at .00001.

e. In 2001, DEA, American Medical Association ("AMA"), and other health organizations released "A Joint Statement" on "Promoting Pain Relief and Preventing Abuse of Pain Medications, a Critical Balancing Act." *See generally* Ex. MC-WV-01522 (2001 Joint Statement). The 2001 Joint Statement said, among other things, that pain was undertreated, and that "[f]or many patients, opioid analgesics—when used as recommended—are the most effective way to treat their pain, and often the only treatment option that provides significant relief." *Id.* at .00001; *see also* 7/2 Tr. (Gilligan) at 113:2–118:17.

f. The AMA is the largest organization representing doctors in America, so it is "significant when they're endorsing a statement." *See* 7/2 Tr. (Gilligan) at 113:11–15. A statement from DEA endorsing the use of opioid medications would be taken seriously by doctors who might otherwise fear enforcement for prescribing opioids. *See id.* at 114:1–15.

g. In 2004, the FSMB released an updated "Model Policy for the Use of Controlled Substances for the Treatment of Pain." *See generally* Ex. DEF-WV-03605 (FSMB 2004 Guidelines). The 2004 FSMB Guidelines stated, among other things, that "[n]otwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be under-treated," and that "the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice." *Id.* at .00001. The 2004 FSMB Guidelines further stated that "[t]he board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." *See id.* at .00003; *see also* 7/2 Tr. (Gilligan) at 119:1–122:13.

h. The FSMB's 2004 Guidelines informed doctors that they would have failed to meet the standards of care if they did not adequately treat patients' pain. *See* 7/2 Tr. (Gilligan) at 121:16–122:2. Because the FSMB was involved with state medical boards and therefore medical licensing, such language had a significant influence on doctors. *See id.*

i. FSMB guidelines had an impact on physician prescribing in West Virginia because FSMB materials were given to West Virginia physicians. *See* 7/7 Tr. (Deer) at 90:8-14.

27. The West Virginia Board of Medicine also promulgated guidelines and took other actions that approved this new standard of care.

a. In 1997, the West Virginia Board of Medicine issued a "Position Statement on the Use of Opioids for the Treatment of Chronic Non-Malignant Pain," which recognized that "opioids are appropriate treatment for chronic non-malignant pain in selected patients" and that "[a] physician need not fear disciplinary action by the Board if complete documentation of prescribing of opioids in chronic non-malignant pain, even in large doses, is contained in the medical records." *See* Ex. MC-WV-01219 (1997 Position Statement by the West Virginia Board of Medicine) at .00001 (emphasis omitted); *see also* 7/2 Tr. (Gilligan) at 98:6–99:18; 5/4 Tr. (Waller) at 149:16–150:5. Dr. Deer testified that all doctors in West Virginia received a copy of the position statement and that it changed their perspectives. *See* 7/7 Tr. (Deer) at 74:2–17, 76:20–22; Ex. DEF-WV-03003.

b. In 2005, the West Virginia Board of Medicine adopted a "Policy for the Use of Controlled Substances for the Treatment of Pain" that encouraged doctors to "view pain management as a part of quality medical practice for all patients with pain, acute or chronic," and recognized that "controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." Ex. MC-WV-01218 (2005 West Virginia Board of Medicine Guidelines) at .00001–.00002; *see also* 7/2 Tr. (Gilligan) at 123:3–124:12; 5/4 Tr. (Waller) at 156:13–158:8. Dr. Deer testified that the policy statement was distributed to all licensed doctors in West Virginia and that the policy statement reinforced and expanded the 1997 position statement. *See* 7/7 Tr. (Deer) at 87:13-17.

c. In 2005, the West Virginia Board of Medicine reprinted in its newsletter sent to every licensed doctor in the state a letter from the West Virginia and other Attorneys General to DEA expressing their concern that there was too much focus on anti-diversion and not enough focus on the treatment of pain. *See* Ex. DEF-WV-3010 (2005 West Virginia Board of Medicine Newsletter) at .00005; *see also* 7/7 Tr. (Deer) at 90:25–91:16, 94:8–23.

d. In 2008, the West Virginia Board of Medicine sent a copy of Dr. Fishman's book *Responsible Opioid Prescribing* to every doctor in the State. *See* Ex. DEF-WV-03616 (2008 West Virginia Board of Medicine Newsletter) at .00006 (stating that the West Virginia Board of Medicine, "in conjunction with the [FSMB]," among other organizations, "was able to distribute [*Responsible Opioid Prescribing*] to every licensed physician and physician assistant in West Virginia").

e. The West Virginia Board of Medicine concluded that *Responsible Opioid Prescribing* should be a guide for doctors' opioid prescribing, and even invited Dr. Fishman to speak at a sponsored event in 2008. *See* R. Knittle 8/27/20 Dep. Designations at 135:6–16, 136:2–23, 137:14–22; *see also* 7/7 Tr. (Deer) at 102:3–9.

f. *Responsible Opioid Prescribing* promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain. *See, e.g.*, Ex. MC-WV-02111 (*Responsible Opioid Prescribing*) at .00008–.00009 (listing as "widely accepted" general principles that "[o]pioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins" and that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient"); *see also* Third Amend. Compl. ¶¶ 315, 569 (admitting that *Responsible Opioid Prescribing* "asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient").

g. In 2013, the West Virginia Board of Medicine issued a "Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain," recognizing that "principles of high-quality medical practice dictate that the people of the State of West Virginia have access to appropriate, safe and effective pain management" and that "opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes." *See* Ex. DEF-WV-01935 (2013 West Virginia Board of Medicine Guidelines) at .00003; *see also* 7/2 Tr. (Gilligan) at 127:18–129:10; 5/4 Tr. (Waller) at 167:3–18.

h. The Board of Medicine adopted these guidelines from the FSMB, and reviewed the guidelines carefully before adopting. *See* R. Knittle 8/27/20 Dep. Designations at 163:1–163:9; 163:15–20.

28. Doctors practicing in West Virginia are expected to be familiar with and seek to follow the guidelines and policy statements issued by the West Virginia Board of Medicine. *See* 5/6 Tr. (Gupta) at 54:24–55:6.

29. The State of West Virginia also passed laws that influenced doctors to prescribe more opioids to patients for chronic pain.

a. In 1998, West Virginia passed the Intractable Pain Act. *See generally* Ex. DEF-WV-03106 (Intractable Pain Act). The Intractable Pain Act made clear to doctors that they could treat chronic non-cancer pain the same way they treated chronic cancer pain, with high doses and without fear of retribution. *See* 7/7 Tr. (Deer) at 80:7–81:1.

b. In 2009, West Virginia passed an amendment to the Intractable Pain Act. *See* 7/7 Tr. (Deer) at 95:24–96:1; *see also* Ex. DEF-WV-03067 (2009 Amendment to Intractable Pain Act). The amendment removed the word "intractable" from the previous legislation, which had the effect of broadening the scope of the legislation and making it easier to treat patients with prescription opioids who did not have severe pain. *See* 7/7 Tr. (Deer) at 97:11–98:11.

30. Defendants played no role in changing the standard of care for the treatment of pain, nor did Defendants endorse changes in the standard of care (unlike DEA, the West Virginia Board of Medicine, and other organizations).

a. Plaintiffs offered no evidence that Defendants issued or endorsed any guidelines or standards that influenced the standard of care for the treatment of pain.

b. Plaintiffs offered no evidence that Defendants engaged in any false or misleading marketing activities that influenced the standard of care for the prescribing of medicines.

c. Dr. Mohr, Plaintiffs' marketing expert, testified that she has no opinion that anything in any marketing communication by a distributor was false or misleading, unlawful, or improper. *See* 6/11 Tr. (Mohr) at 97:3–5, 112:19–21, 123:22–124:10. Dr. Mohr further testified that she did not attempt to evaluate the effect of distributors' alleged marketing practices, if any, on sales of prescription opioids. *See id.* at 97:8–13. Dr. Mohr also admitted "there's nothing improper" or "unusual" about the bare fact that Defendants engaged in "marketing" of their services to pharmacies. *See id.* at 112:19–113:3.

d. Dr. Yingling testified that "a distributor has never influenced [his] own prescribing behavior." 6/16 Tr. (Yingling) at 188.

31. The changes in the standard of care led to an increase in the medical use of prescription opioids. As a result of the change in the standard of care, doctors began to prescribe opioids for a broader range of conditions, most notably, for the long-term treatment of chronic pain.

a. Plaintiffs alleged, and therefore admitted, that "by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions." *See supra* Findings ¶ 23.

b. Such prescribing, Dr. Waller testified, "was the general gestalt at the time given that pain as the fifth vital sign was being implemented in hospitals and as such that it was felt that that was the only lever we had to pull for the treatment of pain." 5/4 Tr. (Waller) at 103:2–20.

a. Dr. Gupta testified that there was a "culture" of "attempting to reduce pain from a scale of whatever to zero for every American, every West Virginian, that they could possibly do." 5/6 Tr. (Gupta) at 90:20–24. Dr. Gupta further testified that there was a "culture" of writing "several more days of prescriptions" than required to treat the given condition, and that it was "a common mistake in the medical profession" to prescribe too many opioid pills for a legitimate need. *Id.* at 89:8–17, 90:5–19.

b. Dr. Keyes testified that, "starting in the late 1990s up through around 2010, doctors increased their prescribing of opioids." *See* 6/14 Tr. (Keyes) at 71:8–10.

c. Dr. Yingling testified that "the addition of pain as the fifth vital sign and the smiley face/happy face diagram shown to patients had the effect of increasing net prescribing of pain medications." *See* 6/16 Tr. (Yingling) at 182:16–20.

d. Dr. Deer testified that West Virginia laws and policies changed the standard of care in West Virginia and led to increased opioid prescribing around the state. *See* 7/7 Tr. (Deer) at 100:6–16. Dr. Deer further testified that West Virginia prescribers prescribed opioid medications more freely in accordance with the guidance that was issued by various bodies in West Virginia, and that the vast majority of these prescribers were acting reasonably based on the information available to them at the time. *See id.* at 100:17–101:7.

e. The State of West Virginia's 2018 Opioid Response Plan stated that "[a] critical factor fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain. From 1999 to 2012, opioid prescribing increased fourfold …. West Virginia has experienced some of the highest rates of opioid prescribing in the nation." Ex. P-44223 (2018 Opioid Response Plan for the State of West Virginia) at .00009. Dr. Gupta testified that the 2018 Opioid Response Plan was based on the best knowledge available. *See* 5/5 Tr. (Gupta) at 187:7–11.

32. The changes in the standard of care led to a particular increase in opioid prescribing in West Virginia, which compared to the nation as a whole has an older population, more workers in industries that lead to pain and injuries, and more people who suffer from conditions that cause or contribute to chronic pain.

a. As of 2016, West Virginia ranked number one per capita in total annual prescriptions for all medicines. *See* 5/6 Tr. (Gupta) at 32:17–33:6; *see also* Ex. DEF-WV-00747 (2018 Public Health in West Virginia Presentation) at .00039.

b. States with large rural populations such as West Virginia have among the highest prescribing rates for opioid analgesics. *See* 6/14 Tr. (Keyes) at 52:24–53:5.

c. The West Virginia population has a high relative prevalence of health conditions that could lead to increased pain, including arthritis, cancer, obesity, and other conditions. *See, e.g.*, 5/6 Tr. (Gupta) at 35:6–14, 36:8–37:11, 37:24–38:2, 51:21–25, 52:1–14, 52:21–53:2; 6/14 Tr. (Keyes) at 54:8–17, 60:4–6; 7/7 Tr. (Deer) at 104:13–105:2

d. The West Virginia population is relatively older and has relatively higher levels of obesity, which tends to generate more needs for pain treatment. *See e.g.*, 5/6 Tr. (Gupta) at 37:21–23, 50:25–51:4, 51:14–18, 52:4–7, 53:15–17; 6/14 Tr. (Keyes) at 59:25–60:3; 7/7 Tr. (Deer) at 104:13–105:13; *see also* 6/14 Tr. (Keyes) at 53:21–54:5 (testifying that rural populations are on average older than urban populations).

e. Manual and physical labor is a significant component of the West Virginia economy and tends to generate more needs for pain treatment. *See, e.g.*, 5/6 Tr. (Gupta) at 47:22–48:2, 50:20–24; 6/14 Tr. (Keyes) at 60:7–10; 7/7 Tr. (Deer) at 105:14–106:2.

f. Given the older population and higher rates of chronic pain, Dr. Keyes "would expect to see higher levels of opioid prescribing in West Virginia than in many other states." *See* 6/14 Tr. (Keyes) at 57:17-21.

33. The factors that led to increased opioid prescribing in West Virginia were magnified in Cabell/Huntington.

a. In 2008, Huntington was identified by the CDC as the "most unhealthy city in the nation," with the highest rates of obesity, heart disease, and diabetes. *See* 6/30 Tr. (Williams) at 35:3–7; 124:13–125:3; *see also* Ex. DEF-WV-00902.

34. The opioid crisis would not have occurred if prescribing opioids had not become standard practice in managing acute and chronic pain. *See* 6/14 Tr. (Keyes) at 82:19–22 ("Q. And then, your view is that the opioid crisis would not have occurred if prescribing opioids had not become standard practice in managing acute and chronic pain, correct? A. That's right.").

35. Although Plaintiffs allege that, in hindsight, the volume of prescription opioids distributed in Cabell/Huntington was "excessive," they offered no evidence of how many prescription opioids should have been distributed in Cabell/Huntington.

a. Dr. McCann disavowed any opinion as to the "right" level of opioid supply in Cabell/Huntington. *See* 5/11 Tr. (McCann) at 66:3–9 ("Q. [Y]ou have not studied the medical needs for Cabell County or the City of Huntington; correct? A. Correct. Q. And you cannot tell this Court how many prescription opioids should have been distributed to Cabell County or the City of Huntington; correct? A. Correct.").

b. Mr. Rafalski disavowed any opinion as to the "right" level of opioid supply in Cabell/Huntington. *See* 5/26 Tr. (Rafalski) at 129:4–7 ("Q. You've not done any kind of analysis of the medical needs for prescription opioids in Cabell County or Huntington relative to the national average; correct? A. That's a correct statement. I did not do that.").

c. Ms. Keller disavowed any opinion as to the "right" level of opioid supply in Cabell/Huntington. *See* 6/15 Tr. (Keller) at 168:11–17 ("Q. So, you're not an expert who can come and tell the Court what volume of opioids was the right volume that should have been prescribed in Cabell-Huntington at any point in time, correct? A. Correct. … I don't offer the opinion of what should be the volume.").

d. Dr. McGuire disavowed any opinion as to the "right" level of opioid supply in Cabell/Huntington. *See* 6/17 Tr. (McGuire) at 48:21–49:1 (admitting that he "did not … determine an appropriate level of distribution of prescription opioids into Cabell and Huntington" as part of his expert analysis).

e. Dr. Keyes testified that she "ha[s] not undertaken a statistical evaluation" of how many prescription opioid pills were needed in Cabell/Huntington and "ha[s] not

undertaken any analysis of the pain needs specifically in Cabell/Huntington." *See* 6/14 Tr. (Keyes) at 19:20–20:10.

36. Pain remains a significant public health issue, and the effective treatment of pain remains an important goal of medicine. *See* 5/4 Tr. (Waller) at 163:9–19 (testifying that "the undertreatment of pain is an issue still in the United States").

37. Prescription opioids continue to be widely prescribed today for the treatment of various forms of pain, but subject to new guidelines. *See infra* Findings ¶¶ 38–39. Such prescribing occurs despite significant attention over the past decade to the risks of abuse and addiction associated with these medicines, reflecting the judgments of the medical community that these FDA-approved medications continue to play an important role in the treatment of pain despite the risks associated with their use. *See, e.g.*, 6/14 Tr. (Keyes) at 108:2–4 (testifying that "physicians are more concerned about addiction now than they were in the 1990s and 2000s").

    a. Dr. Gilligan testified that, since 2013, the standard of care for opioids has become more conservative, and opioid prescribing rates have decreased, and that this change was driven by the medical profession. *See* 7/2 Tr. (Gilligan) at 138:14–139:1. Nevertheless, opioids continue to be prescribed for acute pain, cancer pain, and non-cancer chronic pain. *See id.* at 139:15–25.

    b. Dr. Gupta testified that in recent years, there has been an effort to educate doctors in West Virginia to think more carefully about their prescribing of opioids. *See* 5/6 Tr. (Gupta) at 57:5–8. Dr. Gupta further testified that over time, with more training and better use of databases like the CSMP, doctors in West Virginia are writing fewer prescriptions for opioids. *See id.* at 57:19–58:3.

38. Current guidelines promulgated by the federal Center of Disease Control ("CDC") and West Virginia experts encouraged doctors to prescribe opioids more conservatively than did prior guidelines, while continuing to advise that prescription opioids are appropriate and may be prescribed for treatment of chronic non-cancer pain in certain circumstances, based on a shared decision between the doctor and patient .

    a. In 2016, CDC published its "Guideline for Prescribing Opioids For Chronic Pain." *See* 5/6 Tr. (Gupta) at 58:19–59:3. CDC's 2016 guidelines did not apprise clinicians that they should not use opioids for chronic pain, but rather stated that it is appropriate to use opioid therapy for chronic pain in certain circumstances. *See id.* at 69:20–23, 70:14–20.

    b. CDC's 2016 guidelines did not seek to limit the use of prescription opioids for the treatment of acute pain. *See* 5/6 Tr. (Gupta) at 71:7–15, 71:25–72:4.

    c. Dr. Gupta testified that when CDC issues guidelines on any matter, it is using the best available science and data. *See* 5/6 Tr. (Gupta) at 62:18–25.

d. After CDC issued its guidelines in 2016, the State of West Virginia convened an expert panel to issue its own new pain management guidelines. *See* 5/6 Tr. (Gupta) at 26:2–9.

e. The State of West Virginia's revised pain management guidelines—called the "Safe and Effective Management of Pain Guidelines" or "SEMP" Guidelines—were issued in 2016. *See* 5/6 Tr. (Gupta) at 26:25–27:4. The SEMP guidelines were intended to apprise West Virginia doctors of the standards that should be applied in making prescribing decisions for opioids. *See id.* at 74:21–75:1, 75:25–76:5.

f. Like CDC's 2016 guidelines, the SEMP Guidelines do not preclude the use of opioids for the long-term treatment of chronic non-cancer pain. *See* 5/6 Tr. (Gupta) at 76:6–8. Instead, the SEMP Guidelines recognize that doctors can make the decision to institute or commence opioid treatment for chronic non-cancer pain if they follow procedures outlined in the guidelines. *See id.* at 76:9–13, 78:22–79:3.

g. The SEMP Guidelines were not intended to alter doctors' practices related to the use of opioids outside the setting of chronic non-cancer pain. *See* 5/6 Tr. (Gupta) at 80:25–81:3.

h. The SEMP Guidelines were endorsed by several health professional organizations in West Virginia. *See* 5/6 Tr. (Gupta) at 27:25–28:5.

39. The CDC and SEMP guidelines, along with West Virginia's 2018 Opioid Reduction Act, changed the standard of care in West Virginia toward more conservative opioid prescribing.

a. In 2018, West Virginia enacted the Opioid Reduction Act. *See* Ex. DEF-WV-03054; 7/7 Tr. (Deer) at 117:24–118:9. The Opioid Reduction Act limited how many days' supply of an opioid medication doctors could prescribe to patients and required doctors to inform patients about alternatives to opioid medications and the risks associated with opioid medications. *See* 7/7 Tr. (Deer) at 118:20–120:23.

b. Dr. Deer testified that the 2016 guidelines and the 2018 Opioid Reduction Act changed the standard of care in West Virginia. *See* 7/7 Tr. (Deer) at 121:15–19.

III. Good-Faith Prescribing Drove the Increased Volume of Prescription Opioids

40. To prescribe opioids, doctors must be registered with DEA and licensed by the State. *See* 21 C.F.R. § 1306.03; *see also* 5/6 Tr. (Gupta) at 54:12–15; 7/2 Tr. (Gilligan) at 72:1–25, 96:11–24; R. Knittle 8/27/20 Dep. Designations at 39:7–12, 201:10–12.

41. "The responsibility for the proper prescribing and dispensing of controlled substances," including opioids, "is upon the prescribing practitioner." 21 C.F.R. § 1306.04(a); *see also* 5/26 Tr. (Rafalski) at 116:25–117:4.

42. A prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); *see also* 5/26 Tr. (Rafalski) at 116:20–24.

43. Doctors, in the exercise of their independent medical judgment, determine whether opioids should be prescribed for their patients, in what dose, and for what duration. *See supra* Findings ¶¶ 8–9.

44. Doctors in Cabell/Huntington determined the total volume of prescription opioids that pharmacies in the community ordered from Defendants and then dispensed pursuant to those prescriptions.

a. Ms. Keller testified that prescribing and distribution in Cabell County matched almost perfectly—average opioid pills prescribed was 141.2 pills per person while opioid pills distributed was 142.19 pills per person. *See* 6/15 Tr. (Keller) at 213:8–214:23. Dr. Keller also testified that because ARCOS data "shows shipments by distributors to pharmacies" it is a "reflection of the prescribing because orders ultimately fill prescriptions that are written." *See id.* at 206:17–25.

b. Dr. Gupta testified that the number of prescriptions going to pharmacies is based on the judgment of doctors and other healthcare providers, and that the total volume of prescriptions determines the total volume of pills that could leave pharmacies. *See* 5/6 Tr. (Gupta) at 46:16–47:4, 47:17–21. Dr. Gupta further testified that a critical factor fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain. *See id.* at 85:4–10.

c. Dr. Keyes testified that the high volume of opioid prescriptions that doctors were writing "became the foundation for the overall expansion in the opioid supply and opioid-related harm." *See* 6/14 Tr. (Keyes) at 82:10–18. Dr. Keyes further testified that she is not aware of any occasion where McKesson, Cardinal, or AmerisourceBergen shipped opioids into Cabell/Huntington in excess of the levels prescribed by doctors. *See id.* at 27:4–7.

d. Mr. Rafalski testified that he is not aware of any pills shipped by Defendants "other than in response to a licensed prescriber writing a prescription." *See* 5/26 Tr. (Rafalski) at 131:6–10. Mr. Rafalski further testified that there is "no other way" for distribution to increase other than for doctors to prescribe more opioids. *See id.* at 242:6–20. Mr. Rafalski further testified that pharmacies only dispense prescription opioids in response to prescriptions, and that the number of pills a pharmacy dispenses is directed by the number of prescriptions written by doctors. *See id.* at 131:11–13, 134:7–10.

e. Mr. Rannazzisi testified that the opioid crisis "started with prescriptions," and that "what drives demand for opioids is appropriate medical treatment," not opioid supply. *See* 6/9 Tr. (Rannazzisi) at 87:23–88:1, 89:11–13, 190:8–13.

f. Dr. O'Connell identified high prescribing rates in West Virginia as a leading contributor to the opioid epidemic. *See* 5/28 Tr. (O'Connell) at 116:13–117:8.

g. Dr. McCann testified that prescribing and distribution volume are "two sides of the same coin." *See* 5/11 Tr. (McCann) at 134:24–135:3. Dr. McCann further testified that he was not aware of any evidence that distribution reflected in the ARCOS data exceeded prescriptions. *See id.* at 183:12–15.

h. Dr. Yingling testified that he had no knowledge of any prescription opioid pills that entered Cabell/Huntington without a prescription from a doctor. *See* 6/16 Tr. (Yingling) at 172:2–7.

i. Mayor Williams testified that the number of pills shipped to Cabell/Huntington was the number of pills that physicians prescribed and the number of pills that pharmacies ordered. *See* 6/30 Tr. (Williams) at 78:24–79:3, 80:6–9.

j. Dr. Murphy testified that the volume of prescription opioids was determined by doctors, not distributors. *See* 7/8 Tr. (Murphy) at 64:20–65:13, 66:22–67:4, 74:3–18.

k. Dr. Gilligan testified that shipments prescription opioids have a one-to-one relationship with prescriptions, and that physicians and other prescribing clinicians drove the changes in prescribing both up and down over time. *See* 7/2 Tr. (Gilligan) at 145:24–146:9, 165:20–24.

45. The overwhelming majority of doctors were acting in good faith when they made the decision to prescribe opioids.

a. Dr. Gupta testified that there were more good doctors in West Virginia than bad doctors at any one point in time, and that most doctors' intent in prescribing opioids was to help their patient because "that was the culture. That was the education. That was the influence. That was their understanding." *See* 5/6 Tr. (Gupta) at 93:20–94:10.

b. Dr. Keyes testified that the "overwhelming majority of doctors prescribe opioids to their patients in good faith." *See* 6/14 Tr. (Keyes) at 71:3–7, 76:8–15. Dr. Keyes further testified that a doctor acting in good faith to prescribe an opioid may provide for more pills in the prescription than are needed to meet the medical need for which the pills are being prescribed. *See id.* at 74:23–75:13, 76:16–20.

c. Dr. Waller testified that doctors prescribing opioids for chronic non-cancer pain in the mid-2000s "were acting in good faith." *See* 5/4 Tr. (Waller) at 104:15–20.

d. Mr. Rannazzisi testified to Congress that "99 percent of the doctors are perfect" and "that the overwhelming majority of prescribing in America is conducted responsibly." *See* 6/9 Tr. (Rannazzisi) at 102:4–10, 102:17–21. Mr. Rannazzisi testified that an extremely small fraction of doctors were acting illegitimately, and testified that 99% of prescribers in the United States are treating their patients appropriately. *See id.* at 108:12–23; 6/8 Tr. (Rannazzisi) at 184:21–185:1.

e. While serving as head of DEA's Office of Diversion Control, Mr. Rannazzisi testified before Congress in 2014 that "99.5 percent of the prescribers … are not overprescribing." *See* 6/9 Tr. (Rannazzisi) at 99:17–100:10; *see also* T. Prevoznik 4/17/19 Dep. Designations at 402:4–7, 402:16–403:19.

f. In 2006, DEA stated publicly that "nearly every prescription issued by a physician in the United States is for a legitimate medical purpose." *See* Ex. DEF-WV-03076 (Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52721) at .00007; *see also* 6/9 Tr. (Rannazzisi) at 106:14–107:24.

g. Mr. Rafalski agreed with DEA's assessment that "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes," and that "the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by federal or state law enforcement officials." *See* 5/26 Tr. (Rafalski) at 120:21–121:9. Mr. Rafalski further agreed with Mr. Rannazzisi's assessment that 99% of doctors prescribe opioids for legitimate medical purposes, *id.* at 121:13–19, and testified that the vast majority of doctors are trying to do the right thing, *id.* at 117:23–118:2.

h. Mr. Prevoznik testified by deposition designation on behalf of DEA that DEA believes that the overwhelming majority of prescribing in America is conducted responsibly. *See* T. Prevoznik 4/17/19 Dep. Designations at 401:5–9.

i. Mayor Williams testified that "the vast majority of doctors in Cabell County and Huntington thought they were prescribing opioids appropriately." *See* 6/30 Tr. (Williams) at 82:11–14.

j. Dr. Gilligan testified that increased prescribing was driven by well-intentioned doctors, often primary care doctors, trying to follow what they understood was the right way to treat patients. *See* 7/2 Tr. (Gilligan) at 146:10–21.

k. Dr. Deer testified that doctors who prescribed more opioids in accordance with the changing standard of care were acting reasonably based on the information available. *See* 7/7 Tr. (Deer) at 62:9–14.

46. Pill mills do not explain in any significant way the expansion of opioid prescribing and opioid-related harm in the U.S. *See* 6/14 Tr. (Keyes) at 131:14–22.

47. There is no evidence that ties any of Defendants' shipments to a pill mill in Cabell/Huntington.

a. Dr. McCann did not identify any of Defendants' pharmacy customers as pill mills. *See* 5/11 Tr. (McCann) at 183:16–20.

b. Mr. Rafalski could not identify any pills shipped by Defendants that went to a pill mill doctor or to fill an improper prescription. *See* 5/26 Tr. (Rafalski) at 130:9–131:2.

48. To dispense prescription opioids, pharmacies, hospitals, and other dispensers, together with the pharmacists they employ, must be registered with DEA and licensed by the State. *See* 21 C.F.R. § 1306.06; *see also* 5/26 Tr. (Rafalski) at 131:14–17; 5/11 Tr. (McCann) at 69:2–4; 6/30 Tr. (Williams) at 79:4–6.

49. Pharmacies exercise their independent professional judgment before dispensing opioid prescriptions and other FDA-approved medicines. By law, a pharmacist cannot dispense a prescription opioid without a prescription written by a doctor. Pharmacists have a "corresponding responsibility" to fill only those prescriptions written for a legitimate medical purpose in the usual course of practice. 21 C.F.R. § 1306.04(a).

    a. Mr. Rafalski testified that pharmacists have a corresponding responsibility to doctors in dispensing prescriptions, and that before pharmacists can fill a prescription they are required by DEA regulation to ensure that the prescription is issued for a legitimate medical need and is based on a legitimate doctor/patient relationship. *See* 5/26 Tr. (Rafalski) at 131:24–132:13; 21 C.F.R. § 1306.04(a).

    b. Dr. Yingling testified that pharmacists have a corresponding responsibility to prevent diversion of controlled substances. *See* 6/16 Tr. (Yingling) at 173:2–5.

50. Distributors have no corresponding responsibility to ensure that prescriptions are legitimate.

    a. Mr. Rafalski testified that DEA regulations do not contain any reference to a corresponding responsibility for distributors, and that there is no requirement in the regulations that distributors determine that prescribing decisions are legitimate. *See* 5/26 Tr. (Rafalski) at 117:18–22, 132:17–19.

    b. Dr. Yingling testified that there is a shared responsibility between the prescribing physician, the pharmacist, and the patient to use their medication as prescribed. *See* 6/16 Tr. (Yingling) at 172:22–173:1.

51. Prescription opioids remain on the pharmacy shelves unless and until prescriptions are written for them.

    a. Dr. Gupta testified that an opioid pill cannot leave a pharmacy lawfully unless a prescriber decides to write a prescription and a pharmacist decides to dispense it. *See* 5/6 Tr. (Gupta) at 47:5–9, 47:14–16.

    b. Dr. Keyes testified that no matter how many opioids a distributor ships to a given pharmacy, those opioids are supposed to stay in the pharmacy and not go out to the public without a doctor's prescription. *See* 6/14 Tr. (Keyes) at 83:10–17.

    c. Dr. Yingling testified that no opioid prescription medication is supposed to enter the community without first being prescribed by a doctor and dispensed by a pharmacist. *See* 6/16 Tr. (Yingling) at 171:21–172:1.

d. Dr. Mohr testified that a medicine cannot leave the shelf of a pharmacy without a prescription. *See* 6/11 Tr. (Mohr) at 94:14–95:2.

e. Mayor Williams testified that when pharmacists in Cabell/Huntington dispensed prescription opioids, they did so only to people who had prescriptions from doctors. *See* 6/30 Tr. (Williams) at 79:25–80:5.

52. No Defendant ever distributed prescription opioids to a pharmacy in Cabell/Huntington that was not State-licensed and DEA-registered.

a. Plaintiffs offered no evidence that Defendants ever distributed controlled substances to any entity that did not hold a proper registration from DEA or license from the West Virginia Board of Pharmacy.

b. Dr. McCann was not aware of any evidence that Defendants distributed to pharmacies that were not licensed by DEA or the West Virginia Board of Pharmacy. *See* 5/11 Tr. (McCann) at 69:12–16, 182:21–183:7; 5/12 Tr. (McCann) at 65:14–18.

c. Mr. Rafalski was not aware of Defendants ever supplying a pharmacy that was not licensed by DEA. *See* 5/26 Tr. (Rafalski) at 131:21–23.

d. Mr. Rannazzisi admitted that he could not identify any instance where any Defendant "supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA." *See* 6/9 Tr. (Rannazzisi) at 151:19–23.

e. Dr. Yingling was not aware of any shipments from distributors to anyone in Cabell County other than DEA-registered, state-licensed pharmacies or hospitals. *See* 6/16 Tr. (Yingling) at 173:21–25.

f. Mr. Mays testified that AmerisourceBergen does not ship to customers who are not registered with DEA and licensed by the proper state entity. *See* 5/18 Tr. (Mays) at 173:3-12.

g. Mr. Moné testified that Cardinal Health does not ship to customers who are not registered with DEA and licensed by the State of West Virginia. *See* 5/20 Tr. (Moné) at 180:4–10.

h. Mr. Oriente testified that McKesson does not ship to customers who are not registered by DEA. *See* 5/25 Tr. (Oriente) at 31:4–15.

53. No Defendant ever shipped any prescription opioids to a pharmacy in Cabell/Huntington that the Defendant knew or should have known was dispensing for any purpose other than to fill legitimate prescriptions written by doctors.

a. Plaintiffs offered no evidence that Defendants ever distributed controlled substances to any entity that the Defendant knew or should have known was

dispensing for any purpose other than to fill legitimate prescriptions written by doctors.

b. Mr. Zimmerman testified that if ABDC knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them." *See* 5/12 Tr. at 203:11–17.

c. Mr. Moné testified that Cardinal Health did not ship any prescription opioids to a pharmacy in Cabell/Huntington that Cardinal Health knew or should have known was dispensing for a purpose other than to fill legitimate prescriptions written by doctors. *See* 5/20 Tr. (Moné) at 180:11–16. Mr. Moné further testified that Cardinal Health never shipped an order it believed would be used for other than legitimate medical purposes. *See id.* at 230:10–14.

d. Mr. Oriente testified that, at all relevant times, McKesson blocked and did not ship orders that it identified as likely to be diverted. *See* 5/25 Tr. (Oriente) at 48:4–14, 55:12–20, 126:4–8.

e. Mr. Rafalski could not identify any pills shipped by Defendants that went to a pill mill doctor or to fill an improper prescription. *See* 5/26 Tr. (Rafalski) at 130:9–131:2. Mr. Rafalski also did not know how many of the orders flagged by his methodologies went to fill legitimate medical needs. *See id.* at 216:13–18.

f. Mr. Rannazzisi had no knowledge of any distributions into Cabell/Huntington, and could not identify any orders in Cabell/Huntington that DEA believed should have been blocked by one of the Defendants but were not. *See* 6/9 Tr. (Rannazzisi) at 14:6–17; 6/10 Tr. (Rannazzisi) at 23:5–9. Mr. Rannazzisi further admitted that he could not identify any occasion "where [he] or someone at DEA told … [Defendants] that [they] should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy." *See id.* at 99:10–16.

g. Dr. McCann was not aware of any pills that any distributor shipped that were dispensed without a valid prescription. *See* 5/11 Tr. (McCann) at 183:8–11.

IV. The Role of Health Insurers and Other Payors

54. "Payors" refers broadly to a group of entities including plan sponsors, health insurers, and pharmacy benefit managers. *See* 7/7 Tr. (Hughes) at 224:14–18.

a. Plan sponsors are entities that organize and provide healthcare to their beneficiaries or employees, such as Medicare and Medicaid. *See* 7/7 Tr. (Hughes) at 222:14–19. The State of West Virginia is a plan sponsor via both Medicaid and the Public Employees Insurance Agency. *See id.* at 223:4–8.

b. Health insurers are insurance companies that sell various forms of health insurance services to plan sponsors. *See* 7/7 Tr. (Hughes) at 222:20–223:1, 224:2–4.

c. Pharmacy benefit managers are companies that administer pharmacy benefits for health insurance and plan sponsor organizations. *See* 7/7 Tr. (Hughes) at 224:7–9. They primarily oversee pharmacy reimbursement claims, paying the pharmacy and billing the health insurer. *See id.* at 224:10–13.

55. The overwhelming majority of people in West Virginia and in Cabell/Huntington have health insurance and use that insurance to pay for their prescription drugs.

a. 94% of people in West Virginia have health insurance. *See* 7/7 Tr. (Hughes) at 226:16–17; *see also* 7/12 Tr. (Colston) at 122:19–24. This percentage is likely to be the same in Cabell/Huntington. *See* 7/7 Tr. (Hughes) at 227:24–228:4.

b. In 2019, 96% of all prescription drugs in West Virginia were paid for by health insurance. *See* 7/7 Tr. (Hughes) at 229:22–24, 230:22–231:3. This percentage is likely to be the same in Cabell/Huntington. *See id.* at 231:16–232:7.

56. Payors are only willing to reimburse for prescriptions—including opioids—that are medically necessary, because to do otherwise would raise their costs. *See* 7/7 Tr. (Hughes) at 232:13–24, 233:4–7. West Virginia Medicaid has a written policy that it will cover only medically necessary health services, including prescription opioids. *See id.* at 232:25–233:7.

57. Because of this, payors are incentivized to use the tools at their disposal to ensure that the prescriptions they reimburse (as well as the number of pills in those prescriptions) are, in fact, medically necessary. *See* 7/7 Tr. (Hughes) at 233:8–234:1.

58. Payors have a number of tools they employ to ensure that the prescriptions they reimburse are medically necessary, including retaining physicians who consult on the standard of care and help determine what drugs are covered and at what level. *See* 7/7 Tr. (Hughes) at 234:2–23, 236:15–20.

59. When a payor reimburses for a prescription, including a prescription opioid, that indicates that the payor determined the prescription was medically necessary. *See* 7/7 Tr. (Hughes) at 236:21–237:2.

60. Payors have a number of "prescription management tools" that they can use to affect the prescribing of drugs, including prescription opioids. *See* 7/7 Tr. (Hughes) at 243:22–244:2, 245:14–246:20, 247:17–21, 247:6–248:11. These prescription management tools can be effectively used to limit prescribing opioids. *See* 7/7 Tr. (Hughes) at 248:12–249:2. Only payors can use those prescription management tools. *See* 7/7 Tr. (Hughes) at 244:23–245:3.

61. Payors in West Virginia have only recently restricted coverage for many prescription opioids or implemented prescription management tools to limit the prescribing of these medicines. *See, e.g.*, 7/7 Tr. (Hughes) at 251:7–13, 251:20–252:2, 252:11–124, 254:21–255:4, 255:17–25, 257:19–23, 257:24–258:2.

62. Distributors play no role in payors' decisions on whether to impose prescription management tools and whether to cover certain drugs or treatments, such as opioids or alternative therapies. *See* 7/7 Tr. (Hughes) at 262:3–14.

63. Payors, including the West Virginia Bureau for Medical Services and West Virginia Public Employees Insurance Agency, had access to data that informed them which doctors were prescribing opioids to which patients at what doses and for what durations. Accordingly, those insurers had access to data that allowed them to identify high prescribers and high users of prescription opioids. *See* 7/7 Tr. (Hughes) at 237:3–15, 239:2–240:9, 240:24–241:5.

V. Changes in the Volume of Prescription Opioids Distributed in Cabell/Huntington

64. Huntington is the second largest city in West Virginia and a hub for state-of-the-art health care. *See, e.g.*, 5/11 Tr. (McCann) at 126:9–11; 6/16 Tr. (Yingling) at 201:10–22; 7/28/20 Cabell County Rule 30(b)(6) Dep. Designations at 303:8–22.

65. Patients travel from a broad geographic area to obtain treatment at hospitals in Cabell/Huntington and subsequently fill prescriptions at pharmacies near these hospitals in Cabell/Huntington. *See, e.g.*, 5/11 Tr. (McCann) at 127:3–10, 127:18–25, 128:7–13; 6/16 Tr. (Yingling) at 201:10–14; 6/16 Tr. (Young) at 107:18–24; 7/28/20 Cabell County Rule 30(b)(6) Dep. Designations at 303:2–7, 304:21–23.

66. The volume of prescription opioids dispensed by pharmacies in Cabell/Huntington reflects the volume of prescriptions written by doctors. These prescriptions drove the demand for and volume of prescription opioid orders placed by pharmacies in Cabell/Huntington. *See supra* Findings ¶¶ 40–44.

67. Due to the characteristics of the population of West Virginia and, in particular, Cabell/Huntington, the change in the standard of care led West Virginia and Cabell/Huntington doctors to prescribe an even greater number of opioid pills than doctors in other jurisdictions. *See supra* Findings ¶¶ 32–33.

68. As the standard of care changed again in recent years and the level of opioid prescriptions declined, so too have Defendants' distributions of prescription opioids. The level of prescriptions for opioid medicines dropped by more than 50% in Cabell/Huntington between 2010 and 2018. The volume of prescription opioids shipped by Defendants to Cabell/Huntington decreased at a corresponding rate.

    a. Dr. McCann testified that, as of 2019, shipments of oxycodone and hydrocodone have decreased by roughly half from their peak, and are down to a level similar to what they were in 2005. *See* 5/10 Tr. (McCann) at 67:18–68:12. Dr. McCann further testified that shipments of oxycodone and hydrocodone have continued to decrease since 2019. *See id.* at 67:18–68:2.

    b. Dr. Gupta testified that opioid prescribing in West Virginia decreased by 52% between 2013 and 2019. S*ee* 5/6 Tr. (Gupta) at 58:7–11. Dr. Gupta further testified

that there has been a significant decline in the levels of opioid prescribing in recent years. *See id.*at 58:4–6.

c. Dr. Keyes testified that, between 2011 and 2018, there was a more than 50% decrease in the level of prescribing of prescription opioids in Cabell County, from 186.6 prescriptions per 100 persons in 2011 to 92.1 prescriptions per 100 persons in 2018. 6/14 Tr. (Keyes) at 176:17–25, 177:9–12.

d. Dr. Keller's analysis showed that "after increasing from 1997 to 2010, opioid prescriptions in Cabell County generally fell from 2010 through 2017." *See* 6/15 Tr. (Keller) at 204:25–205:4.

e. Dr. Deer testified that there has been a "major decrease" in prescriptions for opioids in West Virginia since 2011. *See* 7/7 Tr. (Deer) at 123:15–19. Specifically, there has been a decrease of over 61 million doses of prescription opioids since 2011. *See id.* at 124:20–125:4; *see also* Ex. CAH-WV-00850 (2018 West Virginia Board of Pharmacy Controlled Substances Monitoring Program Annual Report) at .00005.

f. Dr. Murphy testified that prescription opioid shipments into West Virginia and across the country began decreasing precipitously after 2011. *See* 7/8 Tr. (Murphy) at 72:22–73:16.

69. Dr. Yingling testified that the use of opioid prescriptions in Cabell County at this time is within the bounds of medically accepted practice. 6/16 Tr. (Yingling) at 170:5–12.

VI. DEA's Role in the Supply of Prescription Opioids

70. The federal government plays a major role in determining the volume of prescription opioids available to the public.

A. DEA Set Aggregate Production Quotas.

71. DEA sets annual aggregate production quotas for each prescription opioid in the United States, based on its determination of the legitimate medical, scientific, research, and industrial needs for prescription opioids in a given year. *See* 21 U.S.C. § 826(a)(1).

a. Stacy Harper-Avilla, the Section Chief of DEA's United Nations Reporting and Quota Section, testified by deposition designation that the aggregate production quota is the maximum amount of a controlled substance that the United States needs for its legitimate medical, scientific and research purposes, and for export and inventory allowances. *See* S. Harper-Avilla 4/11/19 Dep. Designations at 34:22–35:5.

b. Ms. Harper-Avilla further testified that DEA evaluated prescription data as a factor when setting the aggregate production quotas. *See* S. Harper-Avilla 4/11/19 Dep. Designations at 177:3–7.

c. Ms. Harper-Avilla further testified that DEA considered diversion and abuse when determining the aggregate production quotas, including quantifiable internal data on seizures received from state and local law enforcement. *See id.* at 54:21–55:10; 73:23–74:11.

d. Mr. Rannazzisi testified that DEA's aggregate production quotas set the total amount of a specific substance that can be made in the United States, based on DEA's determination of the legitimate medical, scientific, research, and industrial needs for prescription opioids in a given year. *See* 6/8 Tr. (Rannazzisi) at 196:13–22, 197:3–9; 6/9 Tr. (Rannazzisi) at 186:20–25.

e. Mr. Rannazzisi testified that DEA has to set the quotas to ensure that legitimate patients can access the drugs they need. *See* 6/8 Tr. (Rannazzisi) at 197:10–13. Mr. Rannazzisi further testified that DEA could not lower the quotas during the opioid epidemic because doing so would cause shortages for legitimate patients who needed the drugs. *See id*. at 200:6–201:20.

f. Mr. Rafalski testified that DEA is responsible for setting annual quotas for the manufacture of prescription opioids that manufacturers cannot exceed, and that the quotas are set based on the estimated medical, scientific, research, and industrial needs of the United States or for lawful export. *See* 5/26 Tr. (Rafalski) at 144:8–10, 180:7–22; *see also* Ex. DEF-WV-01597 (OIG Report) at .00012. Mr. Rafalski testified that imposing arbitrary limits on opioid production might keep prescription medicines from people who need them. *See* 5/26 Tr. (Rafalski) at 183:11–24.

72. During the relevant timeframe, DEA continually increased the aggregate production quotas for prescription opioids.

a. In September 2019, the DOJ's Office of the Inspector General published a report titled "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids." *See* Ex. DEF-WV-01597 (OIG Report). The OIG Report concluded that "from 2003 to 2013, DEA authorized manufacturers to produce substantial amounts of opioids. For example, the [quota] of oxycodone increased over 400 percent" during that timeframe. *Id.* at .00018; *see also id.* at .00019 Figure 3. Mr. Rafalski did not dispute these findings. *See* 5/26 Tr. (Rafalski) at 181:14–182:1.

b. Mr. Rannazzisi—who was responsible for overseeing DEA's quota unit and signing off on the annual quotas—admitted that the quotas for oxycodone and hydrocodone began rising in the late 1990s and continued to "increase significantly" during his tenure. *See* 6/8 Tr. (Rannazzisi) at 198:5–18, 199:2–4; 6/9 Tr. (Rannazzisi) at 187:20–188:9.

c. Dr. McCann testified that DEA's aggregate production quota for oxycodone in 2010 was at least ten times greater than it was in 1997. *See* 5/12 Tr. (McCann) at 47:1–4.

73. DEA's decision to increase the quotas for prescription opioids year after year was based on its determination that there was an increasing legitimate medical need for opioid medicines. *See* 6/8 Tr. (Rannazzisi) at 199:5–14; 6/9 Tr. (Rannazzisi) at 188:10–14.

74. Distribution of oxycodone and hydrocodone increased commensurate with the increase in DEA's production quotas.

    a. Dr. McCann testified that the volume of oxycodone and hydrocodone distributed in the United States, in West Virginia, and in Cabell/Huntington increased by approximately a factor of ten during the years 1997 through 2010. *See* 5/12 Tr. (McCann) at 47:16–20, 48:2–10, 48:17–22. He further testified that this was in line with the increase in DEA's production quota for oxycodone during that timeframe. *See id*. at 47:1–4.

75. Defendants played no role in DEA's quota-setting process.

    a. Ms. Harper-Avilla testified that DEA is responsible for setting the aggregate production quotas in concert with FDA and other agencies within DOJ and HHS, and that DEA does not consult with distributors in setting the aggregate production quota. *See* S. Harper-Avilla 4/11/19 Dep. Designations at 111:15–21, 112:9–13.

    b. Mr. Zimmerman testified that DEA is responsible for setting quotas based on information provided by manufacturers, and that AmerisourceBergen has never been involved with setting quotas. *See* 5/13 Tr. (Zimmerman) at 160:7–161:24.

    c. Mr. Moné testified that the DEA set annual quotas for the amount of opioids that manufacturers could produce. *See* 5/20 Tr. (Moné) 179:13–17.

    d. Mr. Oriente testified that DEA controls the amount of prescription opioids that manufacturers can make through the quota process, and that McKesson does not play any role in DEA's setting of the quotas. *See* 5/25 Tr. (Oriente) at 31:16–32:5.

76. Defendants did not distribute prescription opioids in excess of the annual quotas set by DEA.

    a. Dr. McCann testified that distributors cannot ship any more prescription opioids than are manufactured pursuant to the quotas set by DEA. *See* 5/12 Tr. (McCann) at 45:19–23.

    b. Mr. Rannazzisi testified that distributors can only ship pills that manufacturers make within the quotas. *See* 6/9 Tr. (Rannazzisi) at 187:8–10.

    c. Dr. Keyes testified that she is not aware of any occasion where McKesson, Cardinal Health, or AmerisourceBergen shipped opioids in excess of the quotas set by DEA. *See* 6/14 Tr. (Keyes) at 26:18–22.

d. Mr. Moné testified that "[i]t would be impossible for Cardinal Health to ship in excess of the quota," and that Cardinal Health did not do so. *See* 5/20 Tr. (Moné) at 179:18–180:3.

77. DEA determined contemporaneously that the overwhelming percentage of prescriptions written for opioid medicines were for a legitimate medical purpose and medical need. *See supra* Findings ¶ 45, 73.

B. DEA Had Access to Comprehensive Shipment Data.

78. Manufacturers and distributors of prescription opioids, including Defendants, are required to report to DEA on a routine basis every shipment of prescription opioids. This reporting is collected in DEA's Automation of Reports and Consolidated Orders System ("ARCOS"). ARCOS is an automated, comprehensive drug reporting system that allows DEA to monitor the flow of DEA-controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level.

a. Mr. Rafalski testified that distributors have a duty to report all of their sales of certain controlled substances to DEA for use in DEA's ARCOS database. *See* 5/26 Tr. (Rafalski) at 199:24–200:1. He further testified that ARCOS data contains all Schedule II and Schedule II narcotic drugs. *Id.* at 61:15-20.

b. Mr. Rannazzisi testified that DEA receives and validates ARCOS data from Defendants. *See* 6/8 Tr. (Rannazzisi) at 156:18–20, 157:12–17.

c. Dr. McCann testified that ARCOS is a portal through which DEA gathers shipment data for certain controlled substances, including prescription opioids, from wholesale distributors. *See* 5/10 Tr. (McCann) at 20:17–21:4, 5/11 Tr. (McCann) at 67:22–68:6.

79. Defendants accurately reported to DEA every shipment of prescription opioids to Cabell/Huntington pharmacies. *See* 5/11 Tr. (McCann) at 79:21–80:4.

a. Dr. McCann opined that each of the datasets he relied on—including ARCOS—was "highly reliable." *See* 5/10 Tr. (McCann) at 32:23–33:1.

b. Dr. McCann testified that Defendants' transactional data matched up with the ARCOS data virtually perfectly. *See* 5/10 Tr. (McCann) at 31:2–18, 5/11 Tr. (McCann) at 72:9–16.

c. Dr. McCann concluded that more than 99.8% percent of Defendants' shipments were reported in both the ARCOS dataset and Defendants' transactional data. *See* 5/10 Tr. (McCann) at 48:8–49:20, 50:4–20, 51:1–21; 5/11 Tr. (McCann) at 72:17–19.

d. Dr. McCann testified that the data that Defendants reported to DEA via ARCOS was accurate with respect to timing of sales, prescription opioids involved,

quantities of opioids distributed, strengths of opioids distributed, and NDC codes involved. *See* 5/11 Tr. (McCann) at 145:24–146:11.

80. DEA had complete information on the total volume of prescription opioids distributed by Defendants and all other distributors, broken down on a pharmacy-by-pharmacy, distributor-by-distributor, and county-by-county basis across the United States, including in Cabell/Huntington.

a. Mr. Rannazzisi testified that DEA has used ARCOS data to monitor the volume of prescription drugs going downstream. *See* 6/8 Tr. (Rannazzisi) at 167:22–25. Mr. Rannazzisi further testified that DEA was able to use ARCOS data to successfully identify high or excessive-volume purchases and determine which retail pharmacies and practitioners were likely to be involved in the illicit distribution of controlled substances via the Internet. *See id.* at 234:7–16; Ex. P-01207 (2008 Testimony to the House Judiciary Committee) at .00008. Mr. Rannazzisi further testified that DEA could use ARCOS data to develop leads and augment investigations. *See* 6/8 Tr. (Rannazzisi) at 235:1–9; Ex. P-01207 (2008 Testimony to the House Judiciary Committee) at .00008.

b. Mr. Prevoznik testified by deposition designation that DEA could use ARCOS data to see each and every bottle of opioids that was transferred from a distributor to a pharmacy. *See* T. Prevoznik 4/17/19 Dep. Designations at 329:3–10. Mr. Prevoznik further testified that ARCOS gave DEA precise information about how much of certain products were being shipped to different geographic areas. *See id.* at 329:15–19. Mr. Prevoznik also testified that ARCOS data helps DEA identify shifts in drug trends. *See id.* at 164:9–14.

c. Dr. McCann testified that DEA was able to use ARCOS data to track distribution on a per capita basis, conduct analyses at zip code and county levels to determine whether specific jurisdictions were above or below average, and analyze distribution to specific pharmacies to determine whether they were above or below average. *See* 5/12 Tr. (McCann) at 10:5–24.

d. Mr. Rafalski testified that DEA can use ARCOS data to determine the volume of opioids supplied by all distributors to a particular county, and analyze whether the county is above or below average. *See* 5/26 Tr. (Rafalski) at 173:11–15, 176:6–16; Ex. DEF-WV-00642 (DEA ARCOS Presentation) at .00021. Mr. Rafalski further testified that DEA can use ARCOS data to track the distribution of specific prescription opioids on a per capita basis year by year, region by region. *See* 5/26 Tr. (Rafalski) at 175:23–25; Ex. DEF-WV-00642 at .00017.

e. Mr. Oriente testified that McKesson provided ARCOS data to DEA containing information on every shipment of controlled substances in Schedules II–IV, including date shipped, volume shipped, and pharmacy recipient. *See* 5/25 Tr. (Oriente) at 35:22–36:15.

f. Mr. May testified that AmerisourceBergen provided ARCOS data to DEA. *See* 5/17 Tr. (May) at 119:9–13; *see also* 5/13 Tr. (Zimmerman) at 153:6–14. And in 2007 AmerisourceBergen also began reporting each and every controlled substances sale it made (whether it was an ARCOS-reportable controlled substance or not) within two days after each shipment was made. *See* 5/17 Tr. (May) at 119:14–25; *see also* 5/13 Tr. (Zimmerman) at. at 153:15–19.

81. DEA knew on a month-by-month basis the total volume of prescription opioids distributed to Cabell/Huntington and knew the total volume distributed to each pharmacy in Cabell/Huntington.

a. Dr. McCann testified that ARCOS data reported by Defendants was contemporaneously available to DEA, and that DEA could use ARCOS data to track state and national trends month over month. *See* 5/11 Tr. (McCann) at 71:13–24; 5/12 Tr. (McCann) at 9:9–14.

b. Mr. Rafalski testified that DEA uniquely has access to all of the ARCOS data submitted by each DEA registrant across the country, and that DEA can use ARCOS data to determine the volume of opioids supplied by all distributors to a pharmacy. *See* 5/26 Tr. (Rafalski) at 173:7–10, 200:2–5. Mr. Rafalski further testified that DEA can use ARCOS data to analyze trends in U.S. and state shipment data over time. *See id.* at 175:18–22; Ex. DEF-WV-00642 (DEA ARCOS Presentation) at .00008.

82. Every two months, DEA publishes online the total volume of prescription opioids delivered to each zip code (by three-digit prefix). Cabell/Huntington had access to this total-volume information.

a. Dr. McCann testified that DEA publishes Retail Drug Summary Reports on its public website every two months. *See* 5/10 Tr. (McCann) at 30:4–19. Those Retail Drug Summary Reports tell the public about the amount of controlled substances distributed by state and zip code, among other things. *See* 5/11 Tr. (McCann) at 146:12–22. Dr. McCann used DEA's public Retail Drug Summary Reports to prepare some of the charts he presented to the Court regarding the distribution volumes of oxycodone and hydrocodone. *See id.* at 146:23–147:1.

b. Dr. McCann was not aware of any limitation that would have prevented Huntington or Cabell County from looking at DEA's Retail Drug Summary Reports as they became available. *See* 5/11 Tr. (McCann) at 148:8–12. Dr. McCcann further testified that the Retail Drug Summary Reports, which date back to 1997, have been publicly available for many years, potentially as early as 1998. *See* 5/12 Tr. (McCann) at 50:5-9.

83. Wholesale distributors were not permitted to access the ARCOS database before 2018, and DEA granted distributors only limited access to certain ARCOS data beginning in 2018.

a. Dr. McCann testified that in or around February 2018, DEA added a new feature to ARCOS to permit companies like Defendants for the first time to view the number of competitors that sold a particular controlled substance to a prospective customer in the last six months. *See* 5/11 Tr. (McCann) at 151:13–152:3.

b. Mr. Rannazzisi testified that Defendants requested ARCOS data from DEA, but DEA refused to provide that data. *See* 6/8 Tr. (Rannazzisi) at 168:18–25.

c. Mr. Rafalski testified that from the earliest days of his employment with DEA there were constant questions raised that distributors wanted access to the full ARCOS data. *See* 5/27 Tr. (Rafalski) at 33:2–5. Nonetheless, DEA refused to allow distributors access to any ARCOS data until 2018. *See* 5/26 Tr. (Rafalski) at 177:4–11. Mr. Rafalski testified that DEA should have provided distributors access to ARCOS data earlier. *See id.* at 177:18–25.

d. Mr. Moné testified that on multiple occasions Cardinal Health requested de-identified ARCOS data from DEA that would enable Cardinal Health "to integrate into its evaluation process who much other distributors were sending to a particular pharmacy." DEA did not provide that information. *See* 5/20 Tr. (Moné) 218:2–24.

e. Mr. Oriente testified that the ARCOS database was not available to McKesson until very recently, when Congress enacted legislation requiring that access. Prior to then, only DEA had access to ARCOS data despite requests from distributors. *See* 5/25 Tr. (Oriente) at 36:16–37:9. Mr. Oriente further testified that since obtaining access, McKesson has found ARCOS to be a useful tool to review customers, and that it would have been useful to have access to this tool earlier. McKesson now uses ARCOS on a daily basis. *See id.* at 37:10–38:1.

f. Mr. Hilliard testified by deposition designation that, during his time of employment with McKesson, only DEA has access to ARCOS data from all distributors. *See* G. Hilliard 1/10/19 Dep. Designations at 332:18–25.

g. Mr. May testified that, before 2018, distributors had access only to public DEA reports that reflected aggregated nationwide data. *See* 5/17 Tr. (May) at 116:17-117:4. It was only after an act of Congress (via the Support Act) in 2018 that AmerisourceBergen was able to access more granular-level ARCOS data. *Id.* at 117:22-118:18.

84. Prior to 2018, the only data available to Defendants (besides their own) was the publicly reported data referenced above. *See supra* Findings ¶ 83.

85. Neither DEA nor the West Virginia Board of Pharmacy has ever advised any Defendant that the volume of prescription opioids it was distributing to its customers in Cabell/Huntington was excessive or inappropriate.

a. Plaintiffs offered no evidence that DEA or the West Virginia Board of Pharmacy ever advised any Defendant that the volume of prescription opioids it was distributing to its customers in Cabell/Huntington was excessive or inappropriate.

b. Mr. Rannazzisi testified that DEA never advised Defendants that their distribution volume was too high. *See* 6/9 Tr. (Rannazzisi) at 92:18–21. Mr. Rannazzisi further admitted that he could not identify any instance where any of the Defendants "supplied prescription opioids to a DEA licensed pharmacy in Huntington or Cabell that the DEA had warned the distributor not to supply." *See id.* at 151:24–152:3.

c. Mr. Rafalski testified that he was not aware of DEA ever telling any distributor that the level of distribution into Huntington/Cabell was improper, or that any specific orders shipped by Defendants into Cabell/Huntington should not have been shipped. *See* 5/26 Tr. (Rafalski) at 179:4–8, 206:21–207:1. Mr. Rafalski further testified that he was not aware that DEA had ever made the judgment that the overall distribution of prescription opioids into Cabell/Huntington should be different, or that the distribution of prescription opioids into Cabell/Huntington by any particular distributor should be different. *See id.* at 179:9–14.

d. Mr. Moné testified that at no point from 2008–2012 did DEA inform Cardinal Health that DEA believed Cardinal Health's shipments to Cabell/Huntington were excessive, or that Cardinal Health's shipments to any particular pharmacy in Cabell/Huntington were excessive. *See* 5/20 Tr. (Moné) at 181:15–25.

e. Mr. Oriente testified that neither DEA nor the State of West Virginia has ever expressed concern to McKesson about its customers in Cabell/Huntington. *See* 5/25 Tr. (Oriente) at 9:24–10:2.

VII. The Closed System of Distribution

86. The Controlled Substances Act ("CSA") establishes a closed system for drugs classified as controlled substances. DEA-registered manufacturers may sell controlled substances only to DEA-registered distributors and pharmacies; DEA-registered distributors may distribute controlled substances only to DEA-registered dispensers (such as pharmacies, hospitals and others); and DEA-registered dispensers may dispense controlled substances only pursuant to prescriptions written by DEA-registered prescribers. *See* 5/26 Tr. (Rafalski) at 16:17–17:11; 6/7 Tr. (Rannazzisi) at 175:15–21, 176:17–19; 5/13 Tr. (Zimmerman) at 152:5–19.

87. Distributors' role in the closed system ends when they deliver controlled substances to DEA-registered pharmacists.

a. Mr. Rafalski testified that "when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point." *See* 5/26 Tr. (Rafalski) at 198:19–23.

b. Mr. Zimmerman testified that distributors' role in the closed system of distribution ends when they finish shipping pills to pharmacies, and that they cannot control what happens to pills after they leave distributors' control. *See* 5/12 Tr. (Zimmerman) at 160:17–21, 161:24–162:21, 201:19–202:3.

c. Mr. May testified that distributors have "zero visibility" into what happens to pharmaceuticals after they leave distributors' possession and arrive at the pharmacy. *See* 5/14 Tr. (May) at 77:11–78:4.

d. Mr. Brown testified by deposition designation that distributors have no role in dispensing or use of prescription opioids after they reach the pharmacy. *See* V. Brown 7/8/20 Dep. Designations at 300:17–21.

88. The closed system of distribution ends with DEA-registered pharmacists, who are authorized to dispense controlled substances outside the closed system to patients provided they present legitimate prescriptions. *See supra* Findings ¶¶ 10, 48–49, 51.

89. It is DEA's responsibility to regulate and oversee the closed system of drug distribution.

a. Mr. Rannazzisi testified that DEA oversees the closed system of distribution and is responsible for registering all entities within the closed system. *See* 6/7 Tr. (Rannazzisi) at 177:9–12; 6/8 Tr. (Rannazzisi) at 210:4–17. Mr. Rannazzisi further testified that the closed system of distribution allows DEA to account for prescription drugs from the manufacturer to the pharmacy to the patient, and that the purpose of the closed system of distribution is to ensure that prescription drugs do not flow into the illicit marketplace. *See* 6/7 Tr. (Rannazzisi) at 174:21–175:14, 177:15–23.

b. Mr. Rafalski testified that DEA oversees the closed system of distribution through the registration process and enforcement of regulations. *See* 5/26 Tr. (Rafalski) at 155:16–156:1. Mr. Rafalski further testified that DEA has the authority to regulate transactions involving the sale and distribution of controlled substances at both the manufacturer and wholesale distributor levels, and that diversion of opioids can result if DEA fails to exercise its obligation to oversee registrants appropriately. *See id.* at 143:1–7, 156:16–19; Ex. MC-WV-01764 (GAO Report) at .00018.

c. Dr. McCann testified that DEA regulates the supply chain for controlled substances. 5/12 Tr. (McCann) at 44:15–18.

90. DEA has the capability to track and monitor the flow of controlled substances throughout the closed system using the ARCOS database. *See supra* Findings ¶¶ 78–81.

91. DEA conducts frequent inspections and audits of DEA-registered manufacturers and distributors.

a. Mr. Rannazzisi testified that DEA periodically inspected Defendants' distribution centers, including at least one days-long or weeks-long inspection every three years. *See* 6/8 Tr. (Rannazzisi) at 176:12–25, 177:10–13. During these inspections, among other things, DEA (1) reviewed Defendants' policies and procedures for maintaining effective controls against diversion, (2) looked at customer diligence files and recordkeeping, (3) performed a full security sweep and security audit,

(4) ensured the alarm systems were up-to-date, (5) ensured that the cage and vault were compliant with federal regulations, and (6) audited certain products. *See id.* at 177:14–24, 179:12–180:5. After the inspection was complete, DEA communicated its findings (both positive and negative) to the distributor. *See id.* at 180:6–19.

b. Mr. Zimmerman testified that DEA routinely audits registrants—sometimes as many as 25 times per year. *See* 5/13 Tr. (Zimmerman) at 164:16–25. Mr. Zimmerman further testified that DEA conducted full inspections every few years. *See id.* These inspections and audits could last days or weeks, and would involve DEA review of procedures to prevent diversion and to meet all requirements of the federal regulations, a review of customer files, and a review of suspicious orders. *See id.* at 166:1–13.

c. Mr. Moné testified that DEA's cyclical inspections occur every three years and involve DEA reviewing the distribution center's records, reviewing the cage and vault, and auditing inventory. *See* 5/20 Tr. (Moné) at 225:2–14. During cyclical inspections, DEA had full access to Cardinal Health's policies and procedures and full access to customer diligence files. *See id.* at 225:15–23. Plaintiffs presented no evidence that Cardinal Health's Wheeling, West Virginia distribution center was ever out of compliance with either the company's policies or DEA regulations.

d. Mr. Oriente testified that DEA had the ability to visit McKesson's distribution centers during the registration or renewal process or any other time it saw fit, and that DEA performed cyclical audits of McKesson's distribution centers approximately every two years. *See* 5/25 Tr. (Oriente) at 13:4–14:3. During those audits, DEA had access and "full visibility" into McKesson's policies and procedures, inventory counts, customer files, and sales and transaction data. *See id.* at 14:4–23. Mr. Oriente testified that McKesson understood it was complying with DEA regulations by virtue of passing these cyclical audits. *See id.* at 126:15–25.

92. DEA also has the ability to inspect DEA-registered dispensers and prescribers. *See* 6/8 Tr. (Rannazzisi) at 176:12–25 (testifying that all registrants receive a full inspection).

93. In West Virginia, each manufacturer, distributor, and pharmacy also must be licensed by the West Virginia Board of Pharmacy. *See* W. Va. Code § 60A-3-302(a); *see also* 5/13 Tr. (Zimmerman) at 152:23–153:5; 5/25 Tr. (Oriente) at 15:10–14, 15:24–16:14.

94. The issuance of a distributor license by the West Virginia Board of Pharmacy means the distributor has operations in compliance with all federal legal requirements applicable to wholesale drug distribution and that the Board is satisfied the distributor is maintaining effective controls against diversion. *See* W. Va. Code § 60A-8-7(c)(1)(I).

95. Defendants have been continually licensed by the West Virginia Board of Pharmacy to distribute controlled substances into West Virginia since at least 1998. *See supra* Findings ¶ 4.

VIII. Misuse and Diversion of Prescription Opioids in Cabell/Huntington

96. Doctors understand that prescription opioids present a known risk of addiction and abuse. *See, e.g.*, 7/2 Tr. (Gilligan) at 49:3–11; *see also* 5/4 Tr. (Waller) at 86:16–21 (testifying that a prescriber would "need to net out the benefits and the risks of prescription opioids" for a particular patient).

97. The risks associated with prescription opioids are printed on their FDA-approved product labels and are available for prescribing physicians and other medical professionals to consult.

a. Product labels must be approved by FDA. *See* 6/11 Tr. (Mohr) at 116:2–12; 7/2 Tr. (Gilligan) at 43:12–20.

b. FDA-approved product labels include information about the use, efficacy, risk profile, and benefits of a particular medication. *See* 6/11 Tr. (Mohr) at 116:13–16; 7/2 Tr. (Gilligan) at 40:18–41:7.

c. Warnings listed on FDA-approved product labels tell doctors the specific identified risks of particular medications so that doctors can take them into account when weighing risks and benefits for a particular course of treatment. *See* 7/2 Tr. (Gilligan) at 43:18–44:3, 44:17–24.

d. Product labels are regularly and periodically updated over time as new information becomes available. *See* 7/2 Tr. (Gilligan) at 41:12–15.

e. FDA-approved product labels for prescription opioids include a black box warning stating that opioids carry a risk of addiction, abuse, and misuse, and counsel doctors to monitor and evaluate a patient's risk of addiction. *See* 7/2 Tr. (Gilligan) at 45:6–15, 47:16–48:5.

f. Doctors take the information included in a black box warning particularly seriously. *See* 7/2 Tr. (Gilligan) at 52:9–22.

g. FDA-approved product labels for prescription opioids also include a warning about the potential for Neonatal Opioid Withdrawal Syndrome, which is also known as Neonatal Abstinence Syndrome or "NAS." *See* 7/2 Tr. (Gilligan) at 48:11–21.

98. Doctors are responsible for weighing the known risks of particular medications like opioids against their benefits, based on the unique circumstances of an individual patient. *See supra* Findings ¶¶ 8–9, 41–43, 96.

a. Dr. Gilligan testified that the risk of addiction from opioids is a serious risk that doctors must weigh against the benefits in making a prescribing decision. *See* 7/2

Tr. (Gilligan) at 49:12–19. Dr. Gilligan further testified that the risk of addiction varies significantly across patients based on many factors including history of substance abuse, family history of substance abuse, psychiatric conditions, and demographic factors. *See id.* at 50:1–20.

b. Dr. Smith testified that a prescribing doctor is best situated to evaluate the risks and benefits of prescribing any drug to a patient, including the risks of addiction. *See* 6/10 Tr. (Smith) at 162:12–20.

99. The medical literature and data do not show a significant incidence of addiction when prescription opioids are used as directed by a doctor for limited periods of time, or for longer periods of time at appropriate dosage levels.

a. Dr. Keyes testified that a small percentage of people who use opioids for medical purposes develop OUD. *See* 6/14 Tr. (Keyes) at 114:2–16.

b. In 2014, Mark J. Edlund and colleagues published an article entitled "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-Cancer Pain: The Role of Opioid Prescription." The Edlund article is respected and relied upon by epidemiologists when performing research on opioid use and OUD, and is not subject to any underlying questions of reliability. *See* 6/11 Tr. (Keyes) at 186:10–11, 187:1–13.

c. The Edlund article was designed to measure the incidence of OUD in medical patients following exposure to different levels of prescribed opioids. *See* 6/14 Tr. (Keyes) at 94:18–22.

d. The Edlund article found that more than 99.8% of patients who were treated with prescription opioids, no matter the dose, did not develop OUD if they were treated for less than 90 days. *See* 6/14 Tr. (Keyes) at 96:16–97:7, 99:1–5.

e. The Edlund article found that when opioids were used for more than 90 days at a low or medium dosage, 98.8 percent of the patients did not develop OUD. *See* 6/14 Tr. (Keyes) at 99:6–14.

f. The Edlund article found that 1.7% of the overall sample population of individuals with chronic non-cancer pain received an opioid prescription for more than 90 days. *See* 6/14 Tr. (Keyes) at 107:5–10.

g. The findings of the Edlund article apply to West Virginia. *See* 6/14 Tr. (Keyes) at 99:19–22.

100. Misuse of prescription opioids, as defined in the medical literature, is the use of prescription opioids either without a prescription or other than as prescribed and directed by a doctor. *See* 6/14 Tr. (Keyes) at 36:3–20.

101. Misuse of prescription opioids may involve, for example, crushing and then either injecting or snorting a prescription opioid pill. *See* 5/6 Tr. (Gupta) at 99:1–6; 6/17 Tr. (Feinberg) at 164:19–165:2.

102. Misuse of prescription opioids can occur when these medicines are diverted to a person for whom they were not prescribed or for an illegitimate, nonmedical purpose. *See* 6/7 Tr. (Rannazzisi) at 178:2–4 (testifying that when drugs are diverted, they are used illicitly).

103. Diversion is the transfer of controlled substances to illicit channels, which includes persons for whom they were not prescribed.

a. Mr. Rannazzisi testified that diversion occurs when a prescription drug "escape[s]" from the closed system of distribution. *See* 6/7 Tr. (Rannazzisi) at 177:24–178:1.

b. Dr. Gupta testified that if someone has controlled substances in their possession but no documentation of a prescription, that means they obtained the controlled substances through illegitimate means, otherwise known as diversion. *See* 5/5 Tr. (Gupta) at 112:8–15.

c. Mr. Cox testified by deposition designation that diversion involves people obtaining a prescription drug and using it an illegal manner. *See* D. Cox 7/15/20 Dep. Designations at 46:2–12.

d. Mr. May testified that "diversion is when there is a criminal act because the pharmaceutical prescription has been taken out of the, the closed system and for purposes that weren't intended." *See* 5/14 Tr. (May) at 72:16–21.

e. Mr. Boggs testified by deposition designation that "[d]iversion is the act of taking pharmaceutical controlled substances out of the closed system of distribution or from legitimate channels and patients." G. Boggs 1/17/19 Dep. Designations at 354:6–12.

104. The licensed distribution of controlled substances is not diversion. *See* D. Cox 7/15/20 Dep. Designations at 51:22–52:8.

105. It is possible for diversion to occur while opioids are under Defendants' control, for example if the opioids are stolen from Defendants' warehouses or delivery trucks.

a. Mr. Rafalski testified that robbery and theft from distributors is a form of diversion that can occur. *See* 5/26 Tr. (Rafalski) at 194:16–19.

b. Mr. Mapes testified that diversion can occur if opioids are stolen from a delivery truck. *See* M. Mapes 7/11/19 Dep. Designations at 223:17–20.

106. There is no evidence that diversion of prescription opioids in Cabell/Huntington occurred while under Defendants' control.

a. Plaintiffs offered no evidence of any diversion in Cabell/Huntington while prescription opioids were under Defendants' control.

b. Mr. Rafalski testified that he is not aware of any robberies or thefts of prescription opioids from distributors in Cabell/Huntington. *See* 5/26 Tr. (Rafalski) at 194:9–195:1.

c. No Defendant ever shipped prescription opioids to recipients in Cabell/Huntington other than DEA-registered and state-licensed recipients. *See supra* Findings ¶ 52.

d. Defendants did not ship more prescription opioids than were ordered by pharmacies and hospitals in Cabell/Huntington based on prescriptions written by doctors. *See supra* Findings ¶ 6.

107. Diversion can also occur at the pharmacy level, for example if pills are stolen from a pharmacy or knowingly dispensed without a prescription. *See* D. Cox 7/15/20 Dep. Designations at 50:16–20.

108. There is no evidence of diversion by Defendants' pharmacy customers in Cabell/Huntington.

a. Plaintiffs offered no evidence of any diversion from Defendants' pharmacy customers in Cabell/Huntington.

b. Mr. Rafalski testified that he is "not offering any opinions about whether diversion occurred at a pharmacy level" in Cabell/Huntington. 5/26 Tr. (Rafalski) at 135:9–13. Mr. Rafalski further testified that he is not aware of DEA ever telling one of the Defendants not to distribute to a pharmacy in Huntington/Cabell. *See id.* at 162:12–15.

c. Dr. Keyes testified that she did not identify any sources of diversion in relation to shipments between distributors and pharmacies. *See* 6/14 Tr. (Keyes) at 68:6–10, 69:18–23.

109. The only evidence of pharmacy-level diversion in Cabell/Huntington is with respect to A-Plus Care Pharmacy in Barboursville, which was "a major source of supply for pharmaceutical diversion to the tri-state area and beyond" and was shut down by local law enforcement in 2014. *See* Ex. P-41220 (Huntington Police Department 2014 Annual Report) at .00019–20; *see also* 5/21 Tr. (Lemley) at 256:6–10 (testifying that A-Plus Care Pharmacy was responsible for 97% of the diverted prescription opioid pills seized in 2014).

110. No Defendant ever supplied the A-Plus Care Pharmacy. *See, e.g.*, 5/26 Tr. (Rafalski) at 15:2–22 (acknowledging that Miami-Luken was the only supplier of the A-Plus Care Pharmacy); 5/12 Tr. (McCann) at 27:6–13.

111. It is also possible for diversion to occur after opioids leave Defendants' control and are subsequently dispensed by pharmacies, including in the following ways:

a. Prescription opioids are diverted from a patient's medicine cabinet, including when sold or given to family or friends or stolen. *See* 5/26 Tr. (Rafalski) at 195:9–15; 6/17 Tr. (Holbrook) at 243:22–244:1; D. Cox 7/15/20 Dep. Designations at 50:21–51:2; M. Mapes 7/11/19 Dep. Designations at 223:21–224:6.

b. Prescription opioids are obtained by patients engaged in "doctor shopping." *See* 5/26 Tr. (Rafalski) at 195:2–8; 6/17 Tr. (Holbrook) at 243:16–18; D. Cox 7/15/20 Dep. Designations at 49:17–50:4.

c. Prescription opioids are obtained by patients who forge a prescription. *See* 6/17 Tr. (Holbrook) at 243:19–21; D. Cox 7/15/20 Dep. Designations at 51:12–14.

d. Prescription opioids are bought from drug dealers. *See* D. Cox 7/15/20 Dep. Designations at 51:3–6.

e. Prescription opioids are unlawfully trafficked into Cabell/Huntington from outside the community. *See, e.g.*, 6/14 Tr. (Keyes) at 11:17–22 (testifying that "in many cases" prescription opioids reach an end user because "criminal traffickers or criminal actors have trafficked the drugs into the community"); 6/17 Tr. (Holbrook) at 242:13–18; 5/27 Tr. (Zerkle) at 151:2–6, 151:19–21.

112. Plaintiffs' theory of harm and misuse depends on the prescription opioids being available in the community where unauthorized persons then obtain and misuse them (*i.e.*, after they have been dispensed by a pharmacy or illegally trafficked).

a. On direct examination, Dr. Keyes testified about a purported relationship between the "opioid-related harms and the supply or exposure of prescription opioids in Huntington/Cabell County." 6/11 Tr. (Keyes) at 204:11–19. On cross-examination, however, Dr. Keyes clarified that when she referred to "exposure" and "supply," she was referring to opioids that are in the community and being used or abused by individuals. *See* 6/14 Tr. (Keyes) at 10:20–25.

b. Dr. Keyes further testified that it is impossible to develop opioid use disorder without having been exposed to opioids, and that the opioid-related harms she identifies all begin with someone ingesting opioids into their body. 6/14 Tr. (Keyes) at 12:7–22.

c. Dr. Gupta testified that NAS can only result from prescription opioid use if the mother is using prescription opioids while the baby is *in utero*. *See* 5/6 Tr. (Gupta) at 102:19–103:16.

113. "Medicine cabinet" diversion—for example, where unused prescription opioid pills dispensed by a pharmacy pursuant to a legitimate prescription are subsequently sold or stolen, or given away to friends, family, or others—is the most common pathway of diversion.

a. Mr. Rannazzisi testified that, on as many as 70 occasions, he gave a presentation stating that the most frequent method of obtaining a pharmaceutical controlled

substance for non-medical use was friends or family for free. *See* 6/10 (Rannazzisi) at 88:13–89:18. Mr. Rannazzisi gave that presentation to Congress, *see id.* at 89:19–21, and confirmed that it represented the government's official position, *see* 6/9 Tr. (Rannazzisi) at 141:3–10.

b. Mr. Rafalski took no issue with statistics showing that "more than three out of four people who misuse prescription painkillers use drugs prescribed to someone else." *See* 5/26 Tr. (Rafalski) at 199:11–18.

c. Dr. Waller testified that as prescriptions increased four-fold between 1999 and 2010, unused pills became increasingly available. *See* 5/4 Tr. (Waller) at 174:9–22. Dr. Waller further testified that more than half of people who misuse prescription opioids report obtaining them from family or friends who have prescriptions. *See id.* at 174:23–175:5.

d. Dr. Gupta testified that doctor overprescribing led to prescription opioids that were unused and ended up being diverted from patients' medicine cabinets. *See* 5/6 Tr. at 91:14–25. Dr. Gupta further testified that it was a "common mistake" in the medical profession to prescribe too many opioid pills for a legitimate medical need. *See id.* at 87:12–88:11, 89:25–90:19.

e. Dr. Keyes testified that the literature reflects that pervasive over-prescribing resulted in unused prescribed opioid medications diverted for monetary value, bartered, or for no cost among family and individuals in a shared social network. *See* 6/14 Tr. (Keyes) at 71:24–72:7, 72:15–73:3. Dr. Keyes further testified that it is common for people to have unused medication from an opioid prescription, and for those unused medications to end up being diverted into illicit channels. *See id.* at 39:17–24.

f. Dr. Keyes testified that studies indicate that the large majority of adults who use opioids non-medically obtain them from friends and relatives or from street-level dealers. *See* 6/14 Tr. (Keyes) at 62:4–17.

g. Mr. Holbrook testified that pills obtained through legitimate means were often diverted, including from break-ins from people seeking drugs from medicine cabinets. *See* 6/17 Tr. (Holbrook) at 198:13–199:7.

h. An article by Dr. Wilson Compton of the National Institute on Drug Abuse, found that "more than half" of individuals who misuse prescription opioids "report obtaining them from family or friends who have prescriptions." Ex. MC-WV-02079 (Compton 2019) at .00006.

114. Defendants have no control over the prescription opioids they ship after those medicines are delivered to the pharmacy or hospital that ordered them, and therefore are not responsible for "medicine cabinet" diversion.

a. Mr. Rafalski testified that "medicine cabinet" diversion is the responsibility of the patient, and that distributors have no control over what happens to a prescription

opioid after it is legitimately written and dispensed. *See* 5/26 Tr. (Rafalski) at 196:7–11 ("Q. You agree that when a patient misuses medication that was prescribed for a legitimate medical use, whether it's giving it away or selling it, the ***patient*** is responsible for that? A. Yes, sir."); *id* at 198:19–22 ("Q. You agree that when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point? A. That's a correct statement.")

b. Mr. Rannazzisi testified that unreasonable volumes in prescriptions can lead to medicine cabinet diversion, and that this can happen even if Distributors do everything they are supposed to. *See* 6/9 Tr. (Rannazzisi) at 141:24–143:23. Mr. Rannazzisi further testified that it is not the role of distributors to "evaluate a patient's legitimate medical need for opioids" and that distributors are not required to "Know [Their] Customer's Customer"—*i.e.*, the patients who obtain prescription medicines from pharmacies. *See id.* at 154:14–20, 155:3–7.

c. Mr. Mapes testified by deposition designation that distributors have nothing to do with opioids that are diverted when they are stolen from friends or family. *See* M. Mapes 7/11/19 Dep. Designations at 224:7–11. Mr. Mapes further testified that Distributors cannot control what happens to pills once they are delivered to pharmacy customers. *See id.* at 224:21–24, 225:2.

d. Mr. Brown testified by deposition designation that diversion and unlawful use of prescription opioids happens after Defendants' role in the chain of supply is over. *See* V. Brown 7/8/20 Dep. Designations at 300:22–24, 301:3–4.

115. Any diversion of prescription opioids that occurred in Cabell/Huntington after the medicines were distributed to and dispensed by pharmacies involved criminal actions of third parties over whom Defendants had no control, including the persons to whom the medicines were prescribed and those involved in diverting the prescription opioids.

a. Diversion of a prescription opioid is a criminal act. *See* 5/26 Tr. (Rafalski) at 195:2–5; 6/17 Tr. (Holbrook) at 243:12–15; D. Cox 7/15/20 Dep. Designations at 47:10–17, 51:19–21, 126:19–127:16, 127:20–21; V. Brown 7/8/20 Dep. Designations at 15:9–10, 39:4–8; R. Knittle 8/27/20 Dep. Designations at 58:18–21.

b. Possession and use of a diverted prescription opioid without a legitimate prescription is a criminal act. *See* D. Cox 7/15/20 Dep. Designations at 47:18–48:3; V. Brown 7/8/20 Dep. Designations at 39:9–13.

116. Congress has charged DEA with coming up with estimates of how much diversion is occurring to inform DEA's decisions about quota-setting. *See* 5/26 Tr. (Rafalski) at 249:11–16, 249:24–25; *see also* 7/8 Tr. (Boberg) at 180:12–22, 182:18–23. Pursuant to that legal obligation, DEA has estimated in the past several years that less than 0.1% of oxycodone and hydrocodone are diverted. 5/26 Tr. (Rafalski) at 250:4–9; *see also* 7/8 Tr. (Boberg) at 183:6–13, 197:1–5.

IX. Suspicious Order Monitoring Programs

117. The CSA provides that (1) every person who manufactures, distributes, or dispenses controlled substances must apply for registration with DEA and periodically renew that registration and (2) registered wholesale distributors may ship controlled substances only to dispensers who have an active registration. *See* 21 U.S.C. §§ 822(a)–(b); 21 C.F.R. § 1301.74(a); *see also supra* Findings ¶¶ 4–5, 40, 48, 52, 86.

118. DEA "shall register an applicant" unless it determines "that the issuance of such registration is inconsistent with the public interest." *See* 21 U.S.C. § 823(b).

119. "In determining the public interest" for purposes of registration, revocation, or suspension, the statute instructs DEA to consider certain factors, including the applicant's "maintenance of effective controls against diversion." *See* 21 U.S.C. § 823(b)(1). The CSA and its implementing regulations thus concern the registration process for wholesale distributors.

120. In assessing the factors set forth in the CSA and its implementing regulations to determine whether a registration should be issued, suspended, or revoked, DEA must determine whether the registered entity has substantially complied with the regulatory provisions. Put differently, substantial compliance with the relevant security requirements may be deemed sufficient by the licensing authority. *See* 21 C.F.R. § 1301.71(b).

121. The factors set forth in the CSA and its implementing regulations largely address the physical handling and security of controlled substances, including specifications for storage areas, cabinets, vaults, cages, alarms, compounding areas, and the like. *See*, *e.g.*, 21 C.F.R. § 1301.72.

122. Defendants at all times complied with regulations concerning the physical handling and security of controlled substances.

a. Plaintiffs offered no evidence that Defendants ever failed to maintain adequate physical security over controlled substances while in their possession and under their control.

b. Mr. Zimmerman described AmerisourceBergen's extensive physical security measures and compliance with related regulations. *See* 5/13 Tr. (Zimmerman) at 166:14–171:2, 172:4–16.

c. Mr. Moné testified concerning the "extensive" physical security requirements and Cardinal Health's compliance with same. *See* 5/20 Tr. (Moné) at 194:18–195:14.

d. Mr. Oriente testified concerning McKesson's compliance with the physical security requirements and how prescription opioids are stored and monitored while under McKesson's control. *See* 5/25 Tr. (Oriente) at 11:11–12:25.

e. Mr. Walker testified by deposition designation regarding the significant physical security measures that McKesson took to prevent diversion from its facilities, including vaults, cages, and alarms. *See* D. Walker 1/10/19 Dep. Designations at 360:16–361:15.

f. Mr. Boggs testified by deposition designation that McKesson maintains physical security over controlled substances while under McKesson's control, including by using cages and vaults and security cameras, among other things. *See* G. Boggs 1/17/19 Dep. Designations at 69:16–18, 69:22–70:11, 70:14–22.

123. As part of the "effective controls" provisions of the CSA, registrants are required to (i) "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and (ii) "inform" DEA "of suspicious orders when discovered." *See* 21 C.F.R. § 1301.74(b). This is the only provision in the CSA regulations that mentions suspicious orders.

124. The federal regulations define "suspicious orders" as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *See* 21 C.F.R. § 1301.74(b); *see also* 5/26 Tr. (Rafalski) at 82:18–83:1, 203:4–9; 6/9 Tr. (Rannazzisi) at 9:25–10:14; M. Mapes 7/11/19 Dep. Designations at 80:8–13.

125. The three criteria contained in DEA's suspicious order regulation—"unusual size," "deviating substantially from a normal pattern," and "unusual frequency"—are the only criteria specified in the regulation for identification of suspicious orders. *See* 6/9 Tr. (Rannazzisi) at 10:4–19. DEA does not have any further guidance as to what constitutes a "suspicious order" beyond the text of the regulation. *See id.* at 11:16–23.

126. DEA did not tell distributors whether or not an order is "suspicious," and rather left that decision to distributors.

a. Mr. Rannazzisi testified that DEA "cannot tell a distributor if an order is suspicious under these criteria," and testified that "[i]t was up to the distributor to make the decision whether an order is suspicious or not." *See* 6/9 Tr. (Rannazzisi) at 11:4–15. Mr. Rannazzisi further testified that DEA never told distributors about customers that were under investigation by DEA because of due process concerns and because it was DEA policy not to disclose ongoing investigations. *See* 6/8 Tr. (Rannazzisi) at 174:6–175:16, 6/10 Tr. (Rannazzisi) at 14:13–15:2, 15:19–16:12.

b. Mr. Rafalski testified that the determination of what constitutes a suspicious order was left to the registrant. *See* 5/26 Tr. (Rafalski) at 82:18–22. Mr. Rafalski further testified that it has been a long-standing rule at DEA not to advise a registrant whether to distributor or dispense a controlled substance, and that during his time at DEA he did not inform a distributor whether a pharmacy customer was under investigation, even if the distributor asked. *See id.* at 159:10–21, 161:10–16.

c. Mr. Mapes testified by deposition designation that the regulation does not explain how to identify an order of unusual size, an order of unusual frequency, or an order that deviates substantially from a normal pattern, and that registrants were

responsible for designing their own suspicious order monitoring systems. *See* M. Mapes 7/11/19 Dep. Designations at 80:14–16, 80:18–22, 80:24, 81:2–4, 81:6–11.

127. The vast majority of orders that meet the technical definition of "suspicious orders" under federal and state regulations (because they are of "unusual size" or "unusual frequency" or deviate "from a normal pattern") are in fact legitimate orders placed by legitimate customers.

a. Mr. Prevoznik, testifying on behalf of DEA, acknowledged that not every order meeting the regulatory definition of "suspicious" is indicative of diversion. *See* T. Prevoznik 4/17/19 Dep. Designations at 307:18–22, 308:1–2, 308:4–5, 308:8–9, 308:11–13, 308:16–17; T. Prevoznik 5/17/19 Dep. Designations at 1206:6–7, 1206:10, 1207:11–13, 1207:16, 1208:21–24, 1209:2. Mr. Prevoznik further testified that there could be legitimate reasons for a pharmacy to place an order of unusual size, unusual frequency, or diverting from a normal ordering pattern. For instance:

i. A pharmacy could legitimately place an order of an unusual size if a new hospital or hospice center opened nearby, *see* T. Prevoznik 5/17/19 Dep. Designations at 1206:12–14, 1206:17, 1206:23–1207:1, 1207:6–9;

ii. A pharmacy could place an order of unusual frequency if there was a new customer base, prescriber, or a new doctor's office opening nearby, *see* T. Prevoznik 5/17/19 Dep. Designations at 1207:18–20, 1207:23–1208:2, 1208:7–13; and

iii. A pharmacy could place orders in an abnormal pattern for legitimate reasons, *see* T. Prevoznik 5/17/19 Dep. Designations at 1209:4–7.

b. Mr. Rafalski testified that there are all kinds of circumstances when an order can meet the regulatory definition of "suspicious" but not be diverted. He acknowledged that he does not know how many orders meeting the regulatory definition of "suspicious" have been diverted over time. *See* 5/26 Tr. (Rafalski) at 204:12–16, 205:8–11, 205:18–22.

c. Mr. Rannazzisi testified that orders falling above a certain threshold are not necessarily suspicious, because the ordering pharmacy may be located next to a cancer center, palliative care center, or hospital. *See* 6/8 Tr. (Rannazzisi) at 111:11–24, 183:22–184:2; 6/9 Tr. at 81:11–13.

d. Mr. Mapes testified by deposition designation that an order of unusual size, frequency, or pattern will not necessarily be diverted. M. Mapes 7/11/19 Dep. Designations at 151:19–22, 152:2, 153:6–9, 153:15.

e. Mr. Zimmerman testified that "suspicious" orders are not "bad" just because they meet the regulatory definition. *See* 5/12 Tr. (Zimmerman) at 179:17–180:16.

f. Mr. Oriente testified that an order meeting the regulatory definition of "suspicious" is not necessarily likely to be diverted and that orders of an unusual size, pattern, or frequency can be legitimate. 5/24 Tr. (Oriente) at 56:6–17. Mr. Oriente further testified that developments in a community such as a pharmacy closing or hospice center opening could lead to legitimate, but unusual, ordering patterns. 5/25 Tr. (Oriente) at 47:2–48:3.

g. Mr. Boggs testified by deposition designation that a suspicious order does not equal a suspicious customer—orders that are of an unusual size or deviate substantially from a normal pattern or frequency are more often than not legitimate and not destined for diversion. *See* G. Boggs 1/17/19 Dep. Designations at 95:24–96:2, 96:4–21. Mr. Boggs further testified that, based on his experience, the assumption that a suspicious order equals a suspicious customer is misplaced. *See id.* at 97:14–17, 97:20–98:2.

128. It is common for a legitimate customer to order different quantities of prescription opioids on different days, to order much higher quantities on some days than others, or to order sporadically throughout the month. *See* 5/25 Tr. (Oriente) at 47:2–18.

129. "Suspicious orders," therefore, are not necessarily orders that are likely to be diverted. Conversely, orders that do not meet the regulatory definition of "suspicious orders" can be diverted. *See, e.g.*, G. Boggs 1/17/19 Dep. Designations at 366:8–23, 367:13–19.

130. Volume alone cannot be used to determine whether a pharmacy order is suspicious or a doctor is prescribing inappropriately.

a. Mr. Rannazzisi testified that DEA "do[esn't] investigate based on quantities," and testified that "the amount of dosage units per prescription will never be a basis for investigation for the overwhelming majority of physicians." *See* 6/9 Tr. (Rannazzisi) at 112:16–113:5, 115:15–23. Mr. Rannazzisi further testified that there is nothing inherently suspicious about being a high prescribing doctor. *See id.* at 197:15–21 (agreeing that "[j]ust because a physician is a pain specialist, that doesn't mean that they're prescribing in any sort of a rogue fashion").

b. Dr. Gupta testified that the West Virginia Board of Medicine would not initiate an investigation of a prescriber simply because he or she was prescribing a high volume of opioids. *See* 5/6 Tr. (Gupta) at 143:11–15.

c. Mr. Prevoznik testified by deposition designation that DEA agreed not all pain clinics diverted controlled substances. *See* T. Prevoznik 4/18/19 Dep. Designations at 492:4–6, 492:9–16, 492:20.

d. Mr. Knittle testified by deposition designation that information on the biggest prescriber or numbers alone "wouldn't tell you anything," because the biggest prescriber could be working at a hospice. *See* R. Knittle 8/27/20 Dep. Designations at 193:5–20. Mr. Knittle further testified that it would be "grossly illegal" for the Board of Medicine to "fish[]" for the "biggest prescribers" of opioids identified through West Virginia's controlled substances monitoring program, and that the

Board only investigated doctors against whom there had been a formal complaint. *See id.* at 191:17–192:7.

e. Dr. McCann evaluated Defendants' shipment data and purported to identify pharmacies with above-average ordering, but admitted that he could not say whether or not all of the shipment charts he discussed during his testimony reflected over-supply or under-supply of prescription opioids. *See* 5/11 Tr. (McCann) at 66:10–13.

f. Dr. Gilligan testified that in order to identify inappropriate prescribing, one needs patient-level information and medical expertise, not just prescribing levels. *See* 7/2 Tr. (Gilligan) at 75:11–23.

131. A reliable suspicious order identification methodology would flag only a small number of orders. *See* 6/7 Tr. (Rannazzisi) at 219:15–17 ("The volume of suspicious orders that should [be reported] is not a huge quantity of orders. It shouldn't be like boxes of orders.").

132. Federal regulations require a distributor to check that its shipments are to DEA-registered pharmacies and prescribers prior to shipment. *See* 21 C.F.R. § 1301.74(a). This license check is the only customer due diligence required of distributors under federal law.

133. Neither the CSA nor its implementing regulations impose any express requirement on Defendants not to ship "suspicious orders."

a. The provision of the current regulations referring to "suspicious orders" does not include any no-shipping language. *See* 21 C.F.R. § 1301.74; *see also* M. Mapes 7/11/19 Dep. Designations at 90:25–91:10, 91:12, 151:7–9, 151:16–17; T. Prevoznik 4/17/19 Dep. Designations at 303:19–304:1.

b. DEA recently proposed amending the CSA's implementing regulations to include, for the first time, a "no-shipping" requirement. *See* 85 Fed. Reg. 69,282, RIN 1117–AB47 (Nov. 2, 2020); *see also* 5/26 Tr. (Rafalski) at 203:13–19. That proposed change would not have been necessary if the regulations already included such a requirement.

c. Mr. Prevoznik testified by deposition designation that the CSA requires distributors to maintain effective controls against diversion but does not state whether or not a distributor could ship a suspicious order. *See* T. Prevoznik 4/17/19 Dep. Designations at 167:5–12.

d. Mr. Rannazzisi testified that, during his time as head of DEA's Office of Diversion Control, he never tried to amend the suspicious order regulation to include language directing distributors not to ship suspicious orders. 6/9 Tr. (Rannazzisi) at 12:9–18.

134. The relevant portions of the West Virginia Controlled Substances Act ("WVCSA") and related regulations are nearly identical to the equivalent provisions of the federal CSA and related regulations.

e. The WVCSA grants authority to the West Virginia Board of Pharmacy ("WVBOP") to issue rules related to wholesale drug distribution. W. Va. Code § 60A-3-301.

f. Rules issued by the WVBOP provide that the registrant "shall design and operate a system to disclose … suspicious orders of controlled substances." W. Va. Code R. § 15-2-5.3.

g. Under the WVCSA, registrants are not required not to ship suspicious orders, to perform any particular due diligence on customers (other than verifying their registration status), or to maintain complete due diligence files for any period of time.

135. Each Defendant operates a "suspicious order monitoring" ("SOM") program to identify, inter alia, orders that meet the regulatory definition of suspicious. *See, e.g.*, 5/26 Tr. (Rafalski) at 60:4–61:9, 74:16–75:23, 207:2–6, 250:23–251:3 (describing Defendants' suspicious order monitoring systems at different times).

136. In summary, the record evidence establishes the following propositions:

a. Defendants reported suspicious orders to the DEA. *See infra* Findings ¶¶ 139; *see also, e.g.*, ABDC-Specific Findings ¶¶ 11–12, 16–18, 33, 113, 115; Cardinal-Specific Findings ¶¶ 10, 25, 34; McKesson-Specific Findings ¶¶ 52, 68, 72.

b. Defendants always blocked (*i.e.*, did not ship) any orders that were likely to be diverted. *See infra* Findings ¶ 141.

c. By no later than 2008, Defendants blocked all suspicious orders. *See infra* Findings ¶ 148.

137. Defendants' SOM programs have evolved over time as technology, diversion trends, and guidance from DEA changed. The evolution of these SOM programs was informed by informal guidance provided by DEA. The guidance was never promulgated in any statute or regulation and therefore did not have the force of law.[6] Though not legally obligated, Defendants nevertheless endeavored in good faith to comply with DEA's

[6] DEA sent a series of letters to registrants in 2006 and 2007 setting out the DEA's new guidance regarding its expectations of distributors. *See* Ex. P-00033, Ex. P-00034. Because these letters did not undergo a notice-and-comment rulemaking, and because there were no changes to the Controlled Substance Act's implementing regulations, this sub-regulatory guidance did not have force of law. *See infra* Conclusions of Law ¶ 102–115.

non-binding, sub-regulatory guidance. *See, e.g.*, 5/13 Tr. (Zimmerman) at 173:3–5; 5/20 Tr. (Moné) at 158:22–159:3; 5/25 Tr. (Oriente) at 34:1–35:2.

138. Since at least 2007, DEA repeatedly advised distributors that it does not tell DEA registrants what their suspicious order monitoring system should be and that the decision whether to ship to a customer is left in the distributors' discretion.

a. Mr. Rafalski testified that the regulations do not prescribe any particular form or style of monitoring system. *See* 5/26 Tr. (Rafalski) at 256:18–23. Mr. Rafalski further testified that there is not one particular "golden rule" for designing a suspicious order monitoring trigger, and that the regulations allow flexibility for a registrant to design a system to meet its business needs and serve its customers. *See id.* at 82:15–17, 83:22–84:11.

b. Mr. Mapes testified by deposition designation that DEA affords registrants the discretion to design a suspicious order monitoring program that is effective. *See* M. Mapes 7/11/19 Dep. Designations at 85:5–8, 85:11.

c. Mr. Prevoznik testified by deposition designation on behalf of DEA that there is more than one way to design and operate a system that can identify and report suspicious orders, and there is no one single feature that makes a suspicious order monitoring system compliant. *See* T. Prevoznik 4/17/19 Dep. Designations at 179:22–180:6. Mr. Prevoznik further testified that DEA leaves it up to the registrant to design a system that works with its own business model and customer base. *See id.* 180:7–11. Mr. Prevoznik further testified that it is a business decision whether to ship any particular order, *see* T. Prevoznik 5/17/19 Dep. Designations at 1236:2–4, 1236:7–9, and that DEA did not provide any industry-wide guidance in 2008 or later as to how to design or implement suspicious order monitoring systems, *see* T. Prevoznik 4/17/19 Dep. Designations at 178:19–23, 179:2–3.

A. Defendants' Pre-2007 Suspicious Order Monitoring Programs

139. Defendants' pre-2007/2008 SOM programs were known as "report and ship" programs or "excessive purchase" programs because Defendants reported all orders meeting the definition of "suspicious orders" under the federal standards and then shipped the orders.

a. Mr. Rafalski testified that prior to 2007–2008, each Defendant operated a Suspicious Order Monitoring System that involved both reporting and shipping orders that met the regulatory definition of "suspicious." 5/26 Tr. (Rafalski) at 60:4–61:9.

b. Mr. Zimmerman testified that, between 1998 and 2007, AmerisourceBergen's suspicious order monitoring program involved daily reporting to DEA of all suspicious orders when discovered, monthly reporting of all suspicious orders that had been reported that month (if the DEA field office desired this second report), and distribution center staff reporting any suspicious orders they saw while packing orders to DEA via a DEA contact form. 5/13 Tr. (Zimmerman) at 46:3–21. Mr.

Zimmerman further testified that, between 1996 and 1998, he worked directly with DEA to develop this program and DEA ultimately approved this program in 1998, as also shown by documentary evidence. *Id.* at 179:8–180:10; Ex. AM-WV-00781 (1998 DEA Letter). This DEA-approved program reported the shipped suspicious orders after they had been shipped. 5/13 Tr. (Zimmerman) at 186:18–21. Mr. Zimmerman further explained that the "ship and report" system protected patient access to medication prescribed by licensed doctors. *Id.* at 49:11–50:2; 186:22–25.

c. Before late 2007, Cardinal Health had a two-step process for complying with its regulatory requirement to report suspicious orders. S. Reardon 11/30/18 Dep. Designations at 506:12–506:19; E. Brantley 11/27/18 Dep. Designations at 529:8–530:18; Ex. CAH-WV-00580 (Cardinal Health "DEA Compliance Manual") at .00046 (outlining the company's process for complying with 21 CFR 1301.74(b)). First, Cardinal Health submitted monthly Ingredient Limit Reports ("ILRs") to DEA. S. Reardon 11/30/18 Dep. Designations 424:18–425:2; Ex. CAH-WV-00580 (Cardinal Health "DEA Compliance Manual") at .00046. Second, and separately from the ILRs, Cardinal Health distribution center personnel—sometimes called "pickers and checkers"—would, as a matter of course, evaluate orders on a daily basis before they were shipped to customers. They were encouraged to investigate orders that appeared excessive and notify DEA "before the order [wa]s shipped." Ex. CAH-WV-00580 (Cardinal Health "DEA Compliance Manual") at .00046; *see* S. Reardon 11/30/18 Dep. Designations 428:7–429:14; *id.* 439; Brantley Dep. Designations 369.

d. Mr. Oriente testified that McKesson's "Section 55" program—which was a precursor to McKesson's updated Controlled Substances Monitoring Program (or, "CSMP")—involved daily reporting to DEA of all orders that met the regulatory definition of "suspicious." *See* 5/25 Tr. (Oriente) at 38:13–39:11, 41:3–13, 42:4–43:4; *see also* Ex. MC-WV-00451 (Section 55 Program Manual). McKesson reported all suspicious orders to DEA through its Section 55 program until 2009. *See* 5/25 Tr. (Oriente) at 43:1–4. Mr. Oriente testified that McKesson's Section 55 program was based on DEA-approved guidelines. *See id.* at 51:16–18.

140. As the regulator, it was DEA's responsibility to determine if any of the reported orders needed further investigation. However, the evidence shows that DEA did not make use of suspicious order reports in performance of its responsibilities.

a. The Department of Justice's Office of the Inspector General concluded that DEA field division staff did not even receive access to the suspicious order report database until 2017, nearly 10 years after it was created, noting that the database was described as a "joke." *See* Ex. DEF-WV-01597 (OIG Report) at .00036.

b. Mr. Rafalski testified that he took no issue with the OIG's conclusion that DEA did not keep individual suspicious order reports sent to field offices. *See* 5/26 Tr. (Rafalski) at 164:23–165:1. Mr. Rafalski additionally did not take issue with the assertion that DEA field division staff did not receive access to the suspicious order database until 2017. S*ee id.* at 167:11–14. Mr. Rafalski further testified that he

could not identify any action DEA took on any suspicious order that Defendants reported for Huntington/Cabell, *see id.* at 206:11–15, and he was not aware of any suspicious order reports regarding pharmacies in Huntington/Cabell that led to any investigation by DEA, *see id.* at 2067:16–20.

c. Mr. Rannazzisi testified that DEA is supposed to follow up on suspicious orders, including through evaluation of the order and the customer. *See* 6/7 Tr. (Rannazzisi) at 215:22–216:6. Although Mr. Rannazzisi testified that it was DEA protocol to investigate suspicious order reports, he could not say that every suspicious order report was investigated. *See* 6/8 Tr. (Rannazzisi) at 112:18–23. Mr. Rannazzisi could not say that DEA even investigated 1% of the suspicious order reports that it received. 6/9 Tr. (Rannazzisi) at 167:3–6 ("Q. … Do you know whether it was more than one percent of suspicious orders reported that resulted in an investigation? Do you know? A. I don't know.").

d. Mr. Prevoznik testified by deposition designation on behalf of DEA that between 2006 and 2015, under the leadership of Mr. Rannazzisi, DEA did not have a published policy that DEA would investigate every suspicious order report it received. *See* T. Prevoznik 4/18/19 Dep. Designations at 558:8–13, 558:16–17. Mr. Prevoznik further testified that not every suspicious order that is reported to a regional office actually results in some sort of investigation. T. Prevoznik 5/17/19 Dep. Designations at 1223:11–14, 1223:17.

141. At all relevant times, Defendants' systems blocked and did not ship orders that were identified as likely to be diverted.

a. Mr. Zimmerman testified that if AmerisourceBergen knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them." *See* 5/12 Tr. (Zimmerman) at 203:11–17.

b. Mr. Moné testified that Cardinal Health never shipped an opioid it believed would be used for other than legitimate medical purposes. *See* 5/20 Tr. (Moné) at 230:10–14; *see also* S. Reardon 11/30/18 Dep. Designations at 534:9–14 (testifying that in his "experience at Cardinal Health over 25 years" he did not "ever see Cardinal Health ship an order that [he] believed would be diverted").

c. Mr. Oriente testified that at all relevant times McKesson blocked orders that it identified as likely to be diverted. *See* 5/25 Tr. (Oriente) at 48:4–14, 55:12–20, 126:4–8.

d. No Plaintiff witness disputed the fact that Defendants always blocked orders identified as likely to be diverted.

142. DEA was aware that Defendants' pre-2007/2008 SOM programs involved reporting suspicious orders after they had been shipped, and did not contemporaneously view those programs as out of compliance with the CSA or its implementing regulations.

a. Mr. Prevoznik testified by deposition designation on behalf of DEA that DEA received and accepted excessive purchase reports from at least 1991 to 2008. *See* T. Prevoznik 4/17/19 Dep. Designations at 85:9–14, 94:2–7. Mr. Prevoznik further testified that DEA was aware that distributors were submitting excessive purchase reports on a regular basis, and that DEA was aware that excessive purchase reports listed orders that had already been shipped. *See id.* at 121:15–19, 127:7–12.

b. Mr. Prevoznik testified by deposition designation on behalf of DEA that, in 1996, Bergen Brunswig advised DEA that it was planning on implementing a new controlled substances monitoring program that involved reporting suspicious orders after they had been shipped. *See* T. Prevoznik 5/17/19 Dep. Designations at 1099:8–20, 1100:1–19. Mr. Prevoznik further testified that DEA approved Bergen Brunswig's controlled substances monitoring program, which involved sending reports of suspicious orders after shipping them. *See id.* at 1107:12–1108:12, 1109:6–14, 1109:24–1110:7, 1127:13–16, 1127:19–1128:3, 1129:6–8, 1129:12–13, 1129:15–20, 1129:23–24, 1134:20–23, 1135:2–6, 1135:11–25.

c. Mr. Rafalski testified that he could not identify a single registrant before 2007 that blocked all suspicious orders. *See* 5/26 Tr. (Rafalski) at 251:4–8. Mr. Rafalski further testified that he was not aware of any DEA personnel having told McKesson that its Section 55 program between 1997 and 2007 violated the CSA or its regulations. *See* 5/27 Tr. (Rafalski) at 12:2–11.

d. Mr. Rafalski acknowledged that his subordinate, agent Kyle Wright, provided sworn testimony in his presence in *United States v. $463,497.72*, *see* 5/26 Tr. (Rafalski) at 259:6–24, that:

   i. DEA was aware that it was standard practice in the industry to file suspicious order reports with DEA while continuing to ship those suspicious orders. *See* 5/26 Tr. (Rafalski) at 259:10–16.

   ii. The practice of shipping and reporting suspicious order had been approved by DEA. *See* 5/26 Tr. (Rafalski) at 259:17–19.

e. In September 2006, Mr. Rannazzisi sent a letter to registrants informing them that "the overwhelming majority of registered distributors act lawfully and take appropriate measure to prevent diversion." Ex. P-00033 (Sept. 27, 2006 "Dear Registrant" Letter) at .00002; *see also* 6/9 Tr. (Rannazzisi) at 17:2–7. Mr. Rannazzisi testified that at the time he sent that letter stating that the overwhelming majority of registered distributors were acting lawfully, he was not aware of any distributor that had a policy in place to block suspicious orders instead of shipping and reporting them. *See* 6/9 Tr. (Rannazzisi) at 17:2–22. Mr. Rannazzisi could not point to any action DEA took against any of the hundreds of distributors that were reporting and shipping suspicious orders prior to 2006. *See id.* at 18:11–14.

f. Mr. Rannazzisi acknowledged that the statement "Excessive Purchase Reports will no longer be accepted" does not appear in any versions of the DEA manual prior to

October 2009. *See* 6/9 Tr. (Rannazzisi) at 35:11–14; *Compare* Ex. P-08861 (1996 DEA Diversion Manual) at .00010–.00012 *with* Ex. DEF-WV-03842 (2009 DEA Diversion Manual) at .00003

g. Mr. Mapes testified by deposition designation that he viewed excessive purchase reports as compliant with the regulations, *see* M. Mapes 7/11/19 Dep. Designations at 92:13–15, 92:23–25, and DEA accepted these excessive purchase reports, *see id.* at 96:12, 96:15, 96:21–22.

B. Defendants' Post-2007 Suspicious Order Monitoring Programs

143. In December 2007, in a letter to industry, DEA stated that it was revoking its prior approval of Defendants' "excessive purchase" SOM programs. Prior to that time, DEA had not issued any guidance stating that excessive order reports should not be submitted or did not comply with the requirements of 21 CFR § 1301.74. *See* T. Prevoznik 4/17/19 Dep. Designations at 122:1–12, 126:18–22, 134:2–9, 136:17–137:2.

144. Prior to 2006/2007, DEA did not issue any guidance to Defendants or other distributors that they should block and not ship orders identified as "suspicious."

a. Mr. Rafalski testified that he could not identify any occasion prior to 2007 where DEA said that any order identified as suspicious should not be shipped. *See* 5/26 Tr. (Rafalski) at 251:9–13. Mr. Rafalski further testified that distributors were not informed that they should not ship orders identified as suspicious until the distributor briefings that took place in 2006–2007, *see id.* at 255:6–12, and that DEA guidance not to ship orders identified as suspicious represented a change in policy during the 2006–2007 timeframe, *see id.* at 256:24–258:3.

b. Mr. Rafalski previously testified under oath that there was no do-not-ship requirement before 2007. *See* 5/26 Tr. (Rafalski) at 252:14–19.

c. Mr. Rannazzisi testified that DEA's guidance concerning blocking suspicious orders was first announced in the final order in the *Southwood* administrative proceeding in 2007. *See* 6/9 Tr. (Rannazzisi) at 46:10–18.

d. Mr. Rannazzisi acknowledged that the statement "the registrant does not fill the order but reports same to their local DEA office" does not appear in any prior versions of the DEA manual prior to October 2009. *See* 6/9 Tr. (Rannazzisi) at 32:13–33:17, 35:15–17; *compare* Ex. P-08861 (1996 DEA Diversion Manual) at .00010–.00012 *with* Ex. DEF-WV-03842 (2009 DEA Diversion Manual) at .00003.

e. Mr. Prevoznik testified by deposition designation on behalf of DEA that during the 2007–2008 time period, it was a "business decision" whether a distributor should ship an order identified as suspicious, and DEA was "not going to direct a registrant don't ship or not ship at that time." *See* T. Prevoznik 4/17/19 Dep. Designations at 170:19–24, 171:3–14.

f. Mr. Zimmerman testified that, prior to 2007, no one at DEA told him to stop shipment of suspicious orders. 5/13 Tr. (Zimmerman) at 196:19–22.

g. Mr. Reardon testified that, in approximately September 2007, DEA's guidance about suspicious orders to Cardinal Health changed. S. Reardon 11/30/18 Dep. Designations at 527:22–528:3; Ex. P-00069.

h. Mr. Oriente testified that DEA's guidance began to change in the year or two before 2008, and that the Rannazzisi letters in 2006 and 2007 changed the guidance as to what was expected of distributors. *See* Tr. 5/25/21 (Oriente) at 34:19–24; 53:24–54:2; 55:4–9. McKesson changed its processes in response to the shift in DEA guidance. *See id.* at 55:10-11.

145. DEA did not seek to change the regulations governing the distribution of controlled substances at the time of its revised guidance in 2007/2008. See 6/9 Tr. (Rannazzisi) at 12:6–18, 13:3–12.

a. Mr. Mapes testified by deposition designation that DEA did not change the suspicious order regulations but did change how it expected distributors to comply with the regulations. *See* M. Mapes 7/11/19 Dep. Designations at 197:14–198:1, 198:8–12. Mr. Mapes further testified that DEA's interpretation of the regulation changed, *see* M. Mapes 7/12/19 Dep. Designations at 518:10–18, and that distributors responded to DEA's changing interpretation by developing programs to address DEA's new expectations, *see id.* at 518:19–23.

146. The change in policy to require blocking of suspicious orders prompted concerns within DEA compliance sectors that confusion would result, since the prior report-only policy had been in place for 35 years. *See* 5/26 Tr. (Rafalski) at 258:10–14.

147. It was not until late 2020 that DEA, for the first time, proposed new regulations that would require distributors to conduct "due diligence" and not to ship orders meeting the regulatory definition of "suspicious orders" unless and until additional due diligence showed that the order was not likely to be diverted. *See* 85 Fed. Reg. 69,282, RIN 1117–AB47 (Nov. 2, 2020). Those new proposed regulations have not yet been approved or taken effect.

148. Consistent with DEA's new guidance, each version of each Defendant's SOM program post-2007/2008 blocked and did not ship orders determined to be "suspicious orders."

a. Mr. Rafalski testified that, since 2007–2008, each Defendant operated a Suspicious Order Monitoring System that blocked and did not ship orders determined to be "suspicious." *See* 5/26 Tr. (Rafalski) at 74:16–75:23, 207:2–6, 250:23–251:3. Mr. Rafalski further testified that if a Suspicious Order Monitoring System was working as designed, there would be an immediate process to determine whether to ship or block an order, and an order would only be shipped once a suspicion of diversion has been cleared. *See id.* at 79:14–25. In response to questioning from the Court, Mr. Rafalski confirmed that starting between 2007 and 2008, each Defendant

designed a Suspicious Order Monitoring System that did "exactly" what he testified a properly-designed system should do. *See id.* at 80:2–9.

b. Mr. Rannazzisi testified that, by 2008, every Defendant had in place a policy that involved blocking suspicious orders. *See* 6/9 Tr. (Rannazzisi) at 13:18–24.

c. Mr. Zimmerman testified that AmerisourceBergen blocked all orders identified as suspicious beginning in 2007. *See* 5/13 Tr. (Zimmerman) at 196:1–3.

d. Mr. Reardon testified that Cardinal Health began developing a new suspicious order monitoring program in late 2007. *See* Reardon Dep. Designations 529:24-530:6. The new program blocked and did not ship suspicious orders. *See* 5/20 Tr. (Moné) at 157:6–158:13, 158:22–159:22.

e. Mr. Oriente testified that McKesson began using its updated CSMP—which blocked all orders identified as "suspicious"—in early 2008. *See* 5/25 Tr. (Oriente) at 9:2–12; 55:12–17, 58:23–59:1; *see also* Ex. MC-WV-00381 (2008 CSMP Manual) at .00006. McKesson began blocking orders because DEA's guidance changed, even though the underlying regulation for suspicious order monitoring did not change. *See id.* at 55:21–24; 127:9–12.

149. Each Defendant presented an overview of the features of its SOM program to DEA and provided a copy of the standard operating procedures of its SOM program to DEA.

a. Mr. Mays testified that, in 2007, DEA was involved in the development of AmerisourceBergen's new suspicious order monitoring system. *See* 5/19 Tr. (Mays) at 46:3–8. He further testified that DEA knew the multiplier AmerisourceBergen was using to determine thresholds, knew AmerisourceBergen's due diligence process, reviewed due diligence files, and reviewed the program generally. *Id.* at 46:3–24. Additionally, in 2007, Mr. Zimmerman stood on stage with DEA representative Michael Mapes and presented AmerisourceBergen's suspicious order monitoring program at an industry conference. *See* 5/13 Tr. (Zimmerman) at 198:7–12; *id.* at 199:22–201:8; Ex. DEF-WV-00001 (Presentation by ABDC at DEA conference); Ex. DEF-WV-02191 (DEA website). Mr. Mapes testified by deposition designation that AmerisourceBergen was asked to present its suspicious order monitoring program to industry because DEA thought this new system was compliant with the CSA. M. Mapes 7/11/19 Dep. Designations at 178:11–16, 178:24–179:1; 181:24–182:2, 182:9–182:18.

b. Mr. Moné testified that, in early 2009, he met with Barbara Boockholdt (Chief of the Regulatory Section of the DEA's Office of Diversion Control) and several DEA diversion investigators. Over the course of a week, Mr. Moné reviewed with them Cardinal Health's suspicious order monitoring system, as revamped in light of DEA's new expectations. *See* 5/20 Tr. (Moné) at 219:11–220:1. That discussion included reviewing the procedures for setting customer thresholds—including any multipliers used—and how Cardinal Health identified and reported suspicious

orders. *Id*. at 220:9–23. After Todd Cameron replaced Mr. Moné in September 2012, Mr. Cameron presented Cardinal Health's suspicious order monitoring program to DEA. *See* G. Quintero Dep. Designations 93:9–19; 5/20 Tr. (Moné) at 16:22–25.

c. Mr. Oriente testified that McKesson gave multiple presentations to DEA that provided an overview of its controlled substance monitoring program, including in July and November 2008. *See* 5/25 Tr. (Oriente) at 101:21–23, 102:4–14, 110:14–111:3, 112:1–7; Ex. MC-WV-00397 (July 2008 presentation to DEA headquarters); Ex. P-42657 (November 2008 presentation to DEA in New Jersey). These presentations provided details about McKesson's SOM program, including how it would block orders, when orders would be reported as suspicious, and how it would conduct customer due diligence. *See* 5/25 Tr. (Oriente) at 104:2–110:8.

150. An order that is never shipped cannot be diverted.

a. Mr. Rafalski testified that a blocked order cannot be diverted. *See* 5/26 Tr. (Rafalski) at 208:3–9. Mr. Rafalski further testified that failing to report a suspicious order to DEA is not what causes diversion. *See id.* at 208:10–12.

b. Mr. Rannazzisi testified that if an order is blocked the medicine cannot go downstream and cannot be diverted. *See* 6/9 Tr. (Rannazzisi) at 13:25–14:5.

151. Defendants reported to DEA, through the ARCOS database, every order of prescription opioids that they shipped to pharmacies and hospitals in Cabell/Huntington. *See supra* Findings ¶¶ 78–81.

152. The transactional data Defendants reported through the ARCOS database provided DEA with all of the information it needed to identify potentially problematic order patterns and was more useful to DEA in identifying potential diversion than suspicious order reports. *See supra* Findings ¶¶ 78–81.

C. Mr. Rafalski's Flagging Analysis Is Not Credible.

153. Mr. Rafalski presented a "flagging analysis" that purported to identify tens of millions of orders as "suspicious" and ones that should not have been shipped. 5/26 Tr. (Rafalski) at 214:6–9. Mr. Rafalski testified that every one of the tens of millions of orders flagged by his methodology was likely to be diverted. 5/26 Tr. (Rafalski) at 104:7–13, 214:13–15.

154. Mr. Rafalski did not employ a reliable methodology and his criticisms of Defendants were not credible. *See infra* Findings ¶¶ 155–165; Additional Witness-Specific Findings ¶¶ 65–76.

155. As an initial matter, Mr. Rafalski did not actually perform the flagging analysis that he presented to the Court—Dr. McCann did. *See* 5/26 Tr. (Rafalski) at 96:1–7. Mr. Rafalski did not speak to Dr. McCann about his flagging analysis before using them in

this case, *see id.* at 211:2–9, 212:21–213:7, and could not identify all of the assumptions made by Dr. McCann in performing the flagging analysis, *see id.* at 213:21–24.

156. On direct examination, Mr. Rafalski presented six methods for flagging suspicious orders. On cross-examination, he admitted that four of those methods (Methods C-F) were "not plausible" and that he would not use them to identify suspicious orders. *See* 5/26 Tr. (Rafalski) at 225:8–12; *see also* 5/27 Tr. (Rafalski) at 10:1–7.

157. With respect to the two remaining methods—Method A and Method B—Method A flags about 72% of all shipments as "suspicious," while Method B flags 28% of all orders. *See* 7/8 Tr. (Boberg) at 177:25–178:13. Two methodologies that purport to do the same thing but offer wildly divergent results cannot both be correct, and this sort of inconsistency undercuts the reliability of the methodologies. *See* 7/8 Tr. (Boberg) at 178:14–24.

158. None of Mr. Rafalski's flagging methodologies implement any Suspicious Order Monitoring System used in the real world. *See* 5/26 Tr. (Rafalski) at 220:14–19.

a. DEA has never used any of Mr. Rafalski's flagging methodologies to identify suspicious orders. *See* 5/26 Tr. (Rafalski) at 222:5–10.

b. Mr. Rafalski has never used any of his flagging methodologies outside of testifying in a lawsuit. *See* 5/26 Tr. (Rafalski) at 223:18–21.

c. Mr. Rafalski created his flagging methodologies for the first time for use in this litigation. *See* 5/26 Tr. (Rafalski) at 222:11–13. Outside of litigation, Mr. Rafalski's flagging methodologies have never been used to identify suspicious orders. *See id.* at 224:11–16.

d. Since presenting the flagging methodologies in this litigation, Mr. Rafalski has not recommended to DEA or anyone else that any of the methodologies should be used to identify suspicious orders. *See* 5/26 Tr. (Rafalski) at 222:25–223:17, 224:4–10.

159. Mr. Rafalski testified that his flagging methodologies ignored the admitted fact that an increase in opioid prescribing by doctors caused a substantial increase in the volume of orders placed by pharmacies in Cabell/Huntington since the beginning of the time-period covered by his analysis. *See* 5/26 Tr. (Rafalski) at 242:6–19.

160. Mr. Rafalski did not actually review any of the orders flagged by his methodologies before issuing his expert report. *See* 5/26 Tr. (Rafalski) at 214:13–15, 215:1–7, 227:20–228:3.

161. Mr. Rafalski did not know what percentage of the orders he identified as likely to be diverted "were actually investigated and … cleared" by Defendants. *See* 5/26 Tr. (Rafalski) at 228:21–229:6.

162. Mr. Rafalski testified that the millions of orders flagged by his methodologies were not necessarily "suspicious orders" within the meaning of the federal regulations. *See* 5/26 Tr. (Rafalski) at 227:25–228:3, 229:24–230:2.

163. Mr. Rafalski did not know how many of the orders flagged by his methodologies went to fill legitimate medical needs. *See* 5/26 Tr. (Rafalski) at 216:13–18. Mr. Rafalski did not perform any analysis of the medical needs for prescription opioids in Cabell/Huntington relative to the national average, and the results of his methodologies do not take account of any estimate of medical needs. *See id.* at 129:4–7, 216:23–217:1.

164. Mr. Rafalski's "Method A" is unreliable in identifying suspicious orders or orders that are likely to be diverted.

a. Using Method A, Mr. Rafalski testified that Defendants should have blocked and not shipped 87-93% of oxycodone and hydrocodone shipments into Cabell/Huntington during the relevant time period. *See* 5/26 Tr. (Rafalski) at 96:17–97:18. This volume of flagged orders is not credible. Further, Mr. Rafalski subsequently back-tracked and said that he did not know how many of the tens of millions of orders flagged by Method A should have been reported to DEA as suspicious. *See id.* at 229:24–230:2.

b. The "Method A" algorithm looks at six months of ordering, and then uses the maximum of those six months and tests whether the seventh month's order exceeds that maximum; the algorithm then moves on to the next month, and tests whether it exceeds the trailing six months. *See* 7/8 Tr. (Boberg) at 168:3–17.

c. Separate from the algorithm used in "Method A," Dr. McCann overlaid a "no due diligence assumption," which means that, after any single order is flagged by the algorithm, all subsequent orders are also flagged. *See* 7/8 Tr. (Boberg) at 169:1–6. This assumption is not part of the "Method A" algorithm, but is added to the results of that algorithm. *See id.* at 169:7–11.

d. Dr. McCann did not provide any basis for this "no due diligence assumption," but indicated in deposition testimony that he was directed to apply the assumption by counsel. *See* 7/8 Tr. (Boberg) at 170:8–14.

e. 96% of all orders flagged by "Method A" are flagged solely do to the application of the "no due diligence assumption," not due to the actual application of the "Method A" algorithm. *See* 7/8 Tr. (Boberg) at 173:21–174:8.

f. Mr. Rafalski agreed that it "wouldn't be a valid exercise for the DEA to attempt to use" Method A to identify diversion. *See* 5/26 Tr. (Rafalski) at 236:19–237:1.

g. "Method A" is not consistent with the methodology described in *Masters Pharmaceuticals* given that Dr. McCann applied his methodology to shipment data, instead of order data, and because he applied an additional assumption not present in *Masters*. *See* 7/8 Tr. (Boberg) at 188:11–189:2.

165. Mr. Rafalski's "Method B" is unreliable in identifying suspicious orders or orders that are likely to be diverted.

a. Using Method B, Mr. Rafalski testified that Defendants should have blocked and not shipped 20-66% of oxycodone and hydrocodone shipments into Cabell/Huntington that were flagged by Method B. *See* 5/26 Tr. (Rafalski) at 89:10–23, 91:6–16, 97:19–23. This volume of flagged orders is not credible.

b. Under Method B, a fixed threshold is established based on the maximum monthly volume of the first six months of shipments. *See* 5/26 Tr. (Rafalski) at 89:10–16. Mr. Rafalski's method assumes that any order exceeding that fixed threshold should be blocked as suspicious and not shipped. *See id.* at 89:10–23, 91:6–16, 97:19–24.

c. The fixed threshold assumed by Method B never changes or increases based on any subsequent developments, including particularly increased levels of prescribing or changes in the standards of care. *See* 5/26 Tr. (Rafalski) at 241:8–25. There is no general acceptance for a methodology to identify suspicious orders that ignores entirely what the medical community is doing in terms of increased legitimate prescriptions. *See id.* at 242:1–5.

d. The "fixed threshold assumption" applied in Method B presumes that there could never be a legitimate reason for ordering to increase, as it freezes the maximum threshold during the first six months of ordering. *See* 7/8 Tr. (Boberg) at 175:11–18.

e. Dr. McCann did not identify support for his "fixed threshold" assumption. *See* 7/8 Tr. (Boberg) at 177:13–14.

f. 89% of all orders flagged by Method B are flagged solely do to the application of the "fixed threshold assumption," not due to the actual application of the underlying Method B algorithm. *See* 7/8 Tr. (Boberg) at 176:21–177:3.

g. Method B is not consistent with the methodology described in *Masters Pharmaceuticals* given that Dr. McCann applied his methodology to shipment data, instead of order data, and because he applied an additional assumption not present in *Masters*. *See* 7/8 Tr. (Boberg) at 188:11–189:2.

X. Trafficking of Illicit Drugs in Cabell/Huntington

166. The drug problem in Cabell/Huntington today is a manifestation of a larger, long-term substance-use-disorder ("SUD") problem involving different drugs and drug crises over many decades.

a. Ms. Colston testified that there is a "broader Substance Use Disorder problem in the United States" that "shifts from drug to drug," with most individuals abusing multiple substances. *See* 7/12 Tr. (Colston) at 145:7–16. Ms. Colston further testified that the current problem in Huntington/Cabell is a substance use disorder crisis, not limited to any single substance. *See id.* at 127:22–25.

b. Dr. Gupta testified that when people are suffering from addiction, they're "always searching for something that they can get that's affordable quickly and available." *See* 5/5 Tr. (Gupta) at 194:18–195:9. Those people are "getting and seeking whatever they can find," which results in polypharmacy deaths (*i.e.*, deaths involving multiple drugs). *See id*.

c. Dr. Keyes testified that the overdose death rates for all drugs in the United States has gradually increased over time and that, for the most part, West Virginia has always been in excess of the national drug overdose death rate. *See* 6/11 Tr. (Keyes) at 199:1–8.

167. Cabell/Huntington has been hard hit by substance abuse disorder, particularly because of challenging socioeconomic conditions in the region.

a. During the 1980s, many of the manufacturing plants that once supported the area's economy began to downsize and close. *See* 5/21 Tr. (Lemley) at 183:17–24; Ex. DEF-WV-00916 (Huntington Drug Market Initiative Six Month Evaluation) at .00004.

b. By 2000, most of the high-paying manufacturing plants that once provided a strong tax base for the City of Huntington were gone. *See* 5/21 Tr. (Lemley) at 184:15–19; Ex. DEF-WV-00916 (Huntington Drug Market Initiative Six Month Evaluation) at .00004.

c. The loss of these high paying jobs pushed the median income to $18,760, well below the national median household income level. *See* 5/21 Tr. (Lemley) at 184:22–185:4; Ex. DEF-WV-00916 (Huntington Drug Market Initiative Six Month Evaluation) at .00004.

d. Mayor Williams testified that continuing economic distress due to coal and manufacturing decline has intensified the spread of opioid use in Huntington. *See* 6/30 Tr. (Williams) at 125:7–126:3.

e. Mr. Brown testified by deposition designation that rural areas of the Appalachia High Intensity Drug Trafficking Area ("Appalachia HIDTA") region have high rates of unemployment, poverty, adult illiteracy, fragmented families, teenage pregnancy, public corruption, and an established tradition of bootlegging moonshine, conditions that make those areas more susceptible to illegal drug activity. *See* V. Brown 7/8/20 Dep. Designations at 236:8–237:6.

168. Cabell/Huntington experienced a marked increase in criminal drug trafficking activity beginning in 2002, due in large part to substantial budget cuts at the Huntington Police Department, including a reduction in staffing by 25% and a total elimination of the drug unit.

a. Mr. Lemley testified that Huntington's decision to cut the police budget by 25% in 2002 led to Huntington becoming a regional distribution hub for illegal drugs. *See* 5/21 Tr. (Lemley) at 233:1–8. Mr. Lemley further testified that the slashing of the

police budget made it apparent to out-of-state drug dealers that they could operate freely in Huntington. *See id.* at 187:1–10, 193:2–6.

169. For decades, there has been an extensive amount of illegal drug trafficking activity in Cabell/Huntington. Illicit drug use and the harms that result from it began in Cabell/Huntington well before the introduction of OxyContin in 1996.

a. Mr. Lemley testified that the Huntington area is an epicenter for illegal drug distribution and that out-of-state drug dealers are still a problem in Huntington today. *See* 5/21 Tr. (Lemley) at 197:22–24, 214:7–11.

b. Mr. Lemley testified that individuals from Michigan, Ohio, Georgia, and Florida infected the Huntington area in the early and mid-2000s, selling various drugs. *See* 5/21 Tr. (Lemley) at 194:8–12. Mr. Lemley further testified that, as of the end of 2010, Huntington had an "open-air drug market" where people were openly selling drugs on the street corner—including cocaine, heroin, and illicit prescription opioids. *See id.* at 114:7–14, 115:23–116:9, 179:14–20. The open-air drug market was a major source of violent crime in that area of the City. *See id.* at 180:24–181:2.

c. Sheriff Zerkle testified that illegal drugs have always existed in Cabell County. *See* 5/27 Tr. (Zerkle) at 92:17–24.

d. Chief Holbrook testified that during his tenure as Chief of the Huntington Police Department from 2007-2014, Huntington was a well-known hub for distribution of illegal drugs. *See* 6/17 Tr. (Holbrook) at 230:23-231:1.

e. Mr. Brown testified by deposition designation that Cabell County and Huntington have always had drug problems. *See* V. Brown 7/8/20 Dep. Designations at 76:1-3, 76:5.

f. Mr. Cox testified by deposition designation that the Huntington area is a well-known regional distribution hub for illegal drugs for the entire Tri-State region, which has resulted in a deterioration of the area with increased slum and blighting conditions. *See* D. Cox 7/15/20 Dep. Designations at 188:10-15, 188:22-189:5, 195:12-196:5, 196:7, 196:9-11.

g. Mr. Cox testified by deposition designation that during his time with the Huntington Violent Crime and Drug Task Force, there was never a time when abuse of illegal drugs was not a problem in Huntington or Cabell County. *See* D. Cox 7/15/20 Dep. Designations at 161:10-21. Mr. Cox further testified that illegal drug use and abuse had been a long-standing problem in Huntington and Cabell County prior to 2012. *See id.* at 162:7-11, 162:13, 162:15-162:19.

170. Cabell/Huntington has had problems with various illegal drugs over the years, including (but not limited to) marijuana, cocaine, crack cocaine, heroin, and methamphetamine. All of these illegal drugs and others have been present in some volume at all relevant times in Cabell/Huntington. *See supra* Findings ¶ 168–69.

a. Sheriff Zerkle testified that crack cocaine was a problem in Cabell County around 2005. *See* 5/27 Tr. (Zerkle) at 171:6–17.

b. Chief Holbrook testified that, around 2007, Huntington had open-air drug markets that involved a variety of drugs, including crack cocaine. *See* 6/17 Tr. (Holbrook) at 194:22-195:6. Crack cocaine, focused in the Fairfield neighborhood, created significant problems, including prostitution, dilapidated housing, quality of life issues, food stamp fraud, and robberies. *See id.* at 197:8-198:1.

c. Chief Holbrook testified that "crack cocaine has been the root of all evil that has affected Huntington." *See* 6/17 Tr. (Holbrook) at 236:11-14.

d. Mr. Brown testified by deposition designation that when Appalachia HIDTA was formed in 1998, marijuana was the primary drug problem in the region. *See* V. Brown 7/8/20 Dep. Designations at 62:18-63:2. Mr. Brown further testified that cocaine and crack cocaine have been threats in the Appalachia HIDTA region from at least 2001 to present day. *See id.* at 72:24-73:3.

e. Mr. Cox testified by deposition designation that he is not aware of any time when marijuana, cocaine, crack cocaine, and methamphetamine were not being illegally sold and abused in Huntington. *See* D. Cox 7/15/20 Dep. Designations at 214:18-21, 215:2, 225:6-10, 236:18-22, 237:2.

171. Drug dealers from Detroit, Columbus, Chicago and other large cities have preyed on Cabell/Huntington. The proximity of Huntington to interstate highways connecting with these other cities has made it a prime target for illegal drug trafficking.

a. Mr. Lemley testified that Huntington is a destination city known and utilized by Detroit gang members and narcotics traffickers to establish heroin distribution points in other parts of the Tri-State region. *See* 5/21 Tr. (Lemley) at 250:12–18, 251:6–10. Mr. Lemley further testified that one of the reasons that drug dealers came to Huntington from Detroit and elsewhere is because they could sell their drugs at a higher price in Huntington. *See id.* at 251:12–16.

b. Sheriff Zerkle testified that drug trafficking organizations from Detroit have operated in Huntington and Cabell County since the 1980s and 1990s. *See* 5/27 Tr. (Zerkle) at 161:5-9. Sheriff Zerkle further testified that heroin is brought into Cabell County by drug traffickers from California, Michigan, Ohio and Chicago. *See id.* at 132:8-11, 162:1-2.

c. Chief Holbrook testified that heroin and other illegal drugs were often brought into Huntington from Detroit. *See* 6/17 Tr. (Holbrook) at 231:2-5. Chief Holbrook further testified that drugs were trafficked from other cities outside of West Virginia, including Columbus. *See id.* at 231:19-21.

d. Mayor Williams testified that Detroit drug dealers and drug dealers from other cities are a significant cause of the opioid problem in Huntington. *See* 6/30 Tr. (Williams) at 127:10–13.

e. Mr. Brown testified by deposition designation that the Appalachia HIDTA's proximity to multiple known drug distribution points is a factor that contributes to illegal drug activity in the region. *See* V. Brown 7/8/20 Dep. Designations at 239:10-17, 19.

f. Mr. Cox testified by deposition designation that to the extent heroin is present in Huntington or Cabell County, it was illegally trafficked by criminal drug trafficking organizations. *See* D. Cox 7/15/20 Dep. Designations at 230:1-7. Mr. Cox further testified that Detroit is the most predominant source of illegal narcotics in Huntington, including illegally diverted prescription opioids. *See id.* at 103:22-104:3, 104:10-21, 125:5-12. Mr. Cox also testified that illegal narcotics are also brought into Huntington from outside cities and states such as Akron, Atlanta, and Florida. *See id.* at 104:10-21.

172. Cabell/Huntington has been referred to as "Little Detroit" due to the high volume of criminal actors from Detroit operating in the area. *See* 5/21 Tr. (Lemley) at 251:1–11; 6/17 Tr. (Holbrook) at 231:6-10; D. Cox 7/15/20 Dep. Designations at 188:10-15, 188:22-189:5, 194:17-195:11.

173. Criminal drug trafficking organizations from outside Cabell/Huntington are responsible for illegally diverting prescription opioids into Cabell/Huntington. *See supra* Findings ¶¶ 168–69, 171.

a. Dr. Keyes testified that drug trafficking organizations and drug dealers illegally supply prescription opioids in Huntington and Cabell County. *See* 6/14 Tr. (Keyes) at 84:8-14.

b. In his work for the Huntington Police Department, Mr. Lemley observed that "[a] good number" of the criminals who committed the crimes that he was tabulating had come from outside West Virginia. *See* 5/21 Tr. (Lemley) at 199:11–15.

c. Sheriff Zerkle testified that drug dealers flew from Huntington to Florida to purchase diverted prescription opioids and bring them back to Huntington. *See* 5/28 Tr. (Zerkle) at 151:2-6, 151:19-21.

d. Chief Holbrook testified that drug trafficking organizations trafficked prescription opioids into Huntington in addition to illegal drugs. *See* 6/17 Tr. (Holbrook) at 242:13-18.

174. Illegally diverted prescription opioids peddled by drug trafficking organizations contributed to the supply of prescription opioids available in the Cabell/Huntington community and any corresponding harms caused by that supply.

a. Dr. Keyes testified that illegal trafficking expands the total supply of prescription opioids. *See* 6/14 Tr. (Keyes) at 85:3-7.

b. Mr. Lemley testified that prescription opioids were trafficked from outside the Huntington area via criminal activity, and that by 2014 Columbus and Detroit were

source cities for heroin and prescription opioids being brought into Huntington. *See* 5/21 Tr. (Lemley) at 247:2–12, 249:1–5.

175. Criminal actors are also responsible for illegally manufacturing counterfeit prescription opioid pills. Those counterfeit pills contributed to the supply of prescription opioids available in the Cabell/Huntington community and any corresponding harm caused by that supply.

a. Dr. Waller testified that higher purity heroin—sometimes laced with fentanyl—was pressed into counterfeit pills, and that drug users often thought they were getting prescription pills and did not know they were actually getting illicit heroin pills. 5/4 Tr. (Waller) at 183:1-21, 184:8–11. By selling counterfeit pills made from heroin or fentanyl, drug dealers could sell drug users the "drug they wanted" at half the price. *See id.* at 184:12-185:2. A counterfeit pill pressed from fentanyl has a much higher potential to cause overdose than a prescription pill of the same size. *See id.* at 187:9-19.

b. Dr. Keyes testified that criminal drug dealers are responsible for making counterfeit prescription opioid pills adulterated with fentanyl. *See* 6/14 Tr. (Keyes) at 42:19-43:1, 85:13-18. Dr. Keyes further testified that counterfeit pills expanded the supply of opioids in Cabell/Huntington. *See id.* at 86:23-87:1.

c. Dr. Smith testified that polysubstance overdose deaths are in part caused by counterfeit pills that appear to be prescription opioids, but contain illicit fentanyl. *See* 6/10 Tr. (Smith) at 153:23–154:8.

d. Chief Holbrook testified that drug trafficking organizations also brought counterfeit pills into Huntington. *See* 6/17 Tr. (Holbrook) at 242:19-21. The drug trafficking organizations create counterfeit pills by taking heroin or fentanyl and pressing it into the shape of a prescription pill. *See id.* at 242:22-25. As a result, people who believed they were taking a prescription opioid might actually be ingesting heroin or fentanyl. *See id.* at 243:1-4.

e. Mr. Brown testified by deposition designation that counterfeit oxycodone pills laced with fentanyl or heroin have become a problem more recently. *See* V. Brown 7/8/20 Dep. Designations at 266:3-9. These counterfeit pills are cheaper to produce compared to pure oxycodone pills. *See id.* at 266:15-267:5.

176. In recent years, the use and abuse of illegal drugs has been the major driver of the opioid-related injury in Cabell/Huntington.

a. Dr. Gupta testified that a major shift from pharmaceuticals to illicit drugs began in 2012 as prescriptions for opioids were beginning to decline. *See* 5/6 Tr. (Gupta) at 82:2-10.

b. Dr. Murphy testified that prescription opioid mortality in West Virginia rose until about 2011, and then began declining. *See* 7/8 Tr. (Murphy) at 82:12-22.

c. Dr. Murphy explained that the increase in opioid mortality in the post-2010 period has been driven by an expansion in the use of heroin and illicit fentanyl. *See* 7/8 Tr. (Murphy) at 77:21-78:2. Dr. Murphy further testified that present-day opioid mortality in West Virginia is overwhelmingly driven by heroin and particularly fentanyl. *See id.* at 83:17-22.

d. Mr. Lemley testified that Huntington saw "a progression" in drug offenses over time. *See* 5/21 Tr. (Lemley) at 129:7–16. As of 2013, the growing use of heroin—not prescription opioids—was the number one threat to Huntington. *See id.* at 200:2–8, 238:1–18.

e. Sheriff Zerkle testified that prescription opioids were more prevalent in Cabell County between 2005 and 2010, but became less prevalent starting in 2016. *See* 5/27 Tr. (Zerkle) at 94:23–95:1, 148:15–20. Sheriff Zerkle further testified that the current drug problems in Cabell County are caused by heroin, methamphetamine and fentanyl. *See id.* at 149:6–17, 154:2–3.

f. Dr. O'Connell testified that currently, heroin, fentanyl, and carfentanil are now the most frequently abused substances in Cabell/Huntington. *See* 5/27 Tr. (O'Connell) at 203:21–204:2.

g. Dr. Smith testified that heroin and illicit fentanyl are driving the recent reported increase of overdose deaths in 2019. *See* 6/10 Tr. (Smith) at 223:24-224:6.

h. Dr. Keyes testified that heroin use and related harms increased in the mid-2000s, surpassing prescription opioids as a cause of opioid-related overdoses starting in 2015. *See* 6/14 Tr. (Keyes) at 39:25-40:8.

i. Dr. Yingling testified that, at present, a higher percentage of overdose deaths in Cabell/Huntington are related to synthetic opioids, such as illicit fentanyl and carfentanil, rather than to prescription opioids. *See* 6/16 Tr. (Yingling) at 171:7-11.

j. Dr. Feinberg testified that, in 2015, the Governor of West Virginia identified heroin as "West Virginia's number one problem." *See* 6/17 Tr. (Feinberg) at 96:23–97:8.

k. Dr. Gilligan testified that the nature of drug abuse has shifted from prescription drugs to heroin and fentanyl. *See* 7/2 Tr. (Gilligan), at 145:14-23.

l. Dr. Deer testified that the opioid crisis in West Virginia has evolved into the abuse of illegal opioids like heroin and fentanyl. *See* 7/7 Tr. (Deer) at 137:21-138:1.

m. Ms. Colston testified that illicit fentanyl is the primary current opioid issue in Cabell County, and that the current drug problems in Cabell County also include non-opioids like methamphetamine and other psychostimulants. *See* 7/12 Tr. (Colston) at 151:23–152:10.

n. Mr. Brown testified by deposition designation that the current threat in the Appalachia HIDTA region is from synthetic opioids and methamphetamine. *See* V. Brown 7/8/20 Dep. Designations at 63:12-18. Of 183 overdose deaths in Cabell County in 2017, 145 involved fentanyl and 62 involved heroin. *See id.* at 163:1-11.

o. Mr. Cox testified by deposition designation that, by the time he left the Huntington Violent Crime and Drug Task Force in May 2015, heroin was the largest drug threat facing Huntington/Cabell. *See* D. Cox 7/15/20 Dep. Designations at 42:14-17, 43:4-5, 43:7-11, 43:22-44:3, 44:5-11.

177. Criminal drug trafficking organizations have made heroin and illicit fentanyl more widely available in Cabell/Huntington, at a higher purity and lower cost. *See infra* Findings ¶¶ 185–187, 192–196.

178. Heroin, illicit fentanyl, and other illegal drugs are trafficked into Cabell/Huntington by illicit drug trafficking organizations from China and Mexico. *See, e.g.*, 5/6 Tr. (Gupta) at 84:14–19; 5/21 Tr. (Lemley) at 204:14–17; 5/27 Tr. (Zerkle) at 130:18–20, 178:19–179:2; V. Brown 7/8/20 Dep. Designations at 38:5–8, 38:15–17, 110:6–21; D. Cox 7/15/20 Dep. Designations at 104:4–9.

179. One reason that illegal drugs are so dangerous is that they are unpredictable and may be adulterated with other substances.

a. Dr. Waller testified that because heroin is illegally manufactured, it is not predictable and can be adulterated by substances like illicit fentanyl. *See* 5/4 Tr. (Waller) at 84:13–18. In contrast, legally manufactured prescription opioids are predictable—a 10 milligram hydrocodone pill will contain 10 milligrams of hydrocodone, and will not be altered or made more lethal by illicit drugs like fentanyl. *See id.* at 83:21–84:7, 84:24–85:2.

b. Mr. Cox testified by deposition designation that one reason illegal drugs are so dangerous is that they can be adulterated with other drugs, and the end-user may be unaware they have been adulterated. *See* D. Cox 7/15/20 Dep. Designations at 321:13-22.

180. Criminal actors have begun lacing heroin with illicit fentanyl or deceptively selling fentanyl as heroin in order to boost profits. As a result, many end-users who overdose on illicit fentanyl are unaware that they were taking fentanyl.

a. In the summer of 2016, an overdose cluster in Huntington was caused by a batch of heroin that had been laced with fentanyl. *See* 5/21 Tr. (Lemley) at 202:25–203:9. During that event, 26 people overdosed after being given free samples of drugs laced with synthetic opioids by a drug dealer from Akron, Ohio. *See* 5/6 Tr. (Priddy) at 226:4–9.

b. Dr. Waller testified that drug dealers often adulterate heroin with synthetic opioids and adulterate other drugs, including cocaine, methamphetamine, and counterfeit

prescription pills. *See* 5/4 Tr. (Waller) at 185:3-12. The practice of lacing other opioids with fentanyl is extending the risk of opioid overdose beyond people who knowingly use opioids, because people are ingesting fentanyl and being harmed by it without knowing they are taking it. *See id.* at 185:13-20, 188:24–189:5.

c. Dr. Gupta testified that fentanyl is often used to cut heroin because it is cheaper and drug dealers can therefore make more money. *See* 5/5 Tr. (Gupta) at 86:12–18; 5/6 Tr. (Gupta) at 83:25–84:6. Dr. Gupta further testified that a person using heroin is often not aware that the heroin may have been cut with fentanyl, and that it's "basically Russian roulette every time you use heroin" because it may be laced with fentanyl. *See id.* at 86:12–18; 5/6 Tr. (Gupta) at 84:20–24, 86:12–18.

d. Ms. Priddy testified that drug cartels lace heroin, cocaine, methamphetamine, and other non-opioid drugs with fentanyl. *See* 5/6 Tr. (Priddy) at 225:19–226:1.

e. Mr. Lemley testified that drug cartels have laced fentanyl with heroin in Huntington, and that individuals who may not be seeking opioids may come into contact with fentanyl when it is used to adulterate other illicit drugs like cocaine. *See* 5/21 Tr. (Lemley) at 242:23–243:3, 243:8–12. Mr. Lemley further testified that using a strong opioid like fentanyl increases the likelihood of overdose. *See id.* at 243:13–16.

f. Dr. Keyes testified that criminal drug dealers are responsible for adulterating heroin and other drugs with synthetic opioids. *See* 6/14 Tr. (Keyes) at 44:3–18. Dr. Keyes further testified that many drug users who are taking heroin are unaware that the heroin has been adulterated with fentanyl, which creates added risks. *See id.* at 45:6-9, 45:19–23.

g. Mr. Brown testified by deposition designation that Mexican cartels mix fentanyl into heroin, leading to an increase in overdose deaths. *See* V. Brown 7/8/20 Dep. Designations at 147:4-23.

181. Methamphetamine and cocaine overdose deaths in West Virginia have increased in recent years. See 6/10 Tr. (Smith) at 199:18–201:5; 6/14 Tr. (Keyes) at 44:6–18; 7/12 Tr. (Colston) at 126:17–24 (testifying that psychostimulants are the most common drug involved in overdoses today in Cabell County).

182. Defendants do not distribute any illegal drugs such as cocaine, methamphetamine, heroin, or illicit fentanyl (*i.e.*, synthetic fentanyl illegally manufactured by criminal enterprises and not pursuant to lawful FDA approval). *See* V. Brown 7/8/20 Dep. Designations at 71:9–12, 73:4–6, 111:2–3, 111:6, 144:10–16; D. Cox 7/15/20 Dep. Designations at 164:7–12.

183. Criminal actors necessarily stand between Defendants' licensed shipment of FDA-approved opioid medicines and any harm caused by the use and abuse of illicit drugs. *See* 6/14 Tr. (Keyes) at 205:9–206:15.

XI. Heroin/Fentanyl Abuse in Cabell/Huntington

184. Heroin was trafficked and abused in Cabell/Huntington prior to the current opioid crisis.

a. Mr. Lemley testified that heroin was present in Huntington prior to 2013. *See* 5/21 Tr. (Lemley) at 240:2–19.

b. Dr. Courtwright testified that there were previously two heroin epidemics in the United States, one in the late 1940s and early 1950s, and one in the late 1960s and early 1970s. *See* 5/5 Tr. (Courtwright) at 26:1–6.

c. Dr. Keyes testified that heroin has been prevalent in the United States at various levels and at various times for as long as the country has been focused on drug abuse. *See* 6/14 Tr. (Keyes) at 211:22–212:2.

d. Mr. Brown testified by deposition designation that that heroin was trafficked into the Appalachia HIDTA region by Mexican trafficking organizations since before 2000. *See* V. Brown 7/8/20 Dep. Designations at 110:6–21. Heroin was a threat in the Appalachia HIDTA region before the increase in prescription opioid diversion that occurred in the area. *See id.* at 299:2–6.

185. Since 2012, there has been an increase in the level of heroin overdoses in Cabell/Huntington.

a. Dr. Gupta testified that 2012–2013 was the "sentinel time" when West Virginia saw a spike in heroin deaths, and that heroin deaths started to increase significantly in West Virginia from 2012 onward. *See* 5/5 Tr. (Gupta) at 82:9–83:3, 83:17–84:6.

b. Dr. Smith testified that heroin began to drive overdose deaths in Huntington-Cabell in 2011. *See* 6/10 Tr. (Smith) at 135:25–136:5, 158:6–16. Heroin accounted for approximately one-half of all fatal overdoses in Cabell County from 2013-2015 and one-third of all fatal overdoses in Cabell County from 2016-2018. *See id.* at 202:9-18.

c. Dr. Keyes testified that, starting in 2012, heroin overdoses started to increase in Cabell County. *See* 6/11 Tr. (Keyes) at 202:7–15.

d. Dr. Murphy testified that national heroin mortality began increasing around 2010, peaked in 2015, and then began declining. 7/8 Tr. (Murphy) at 81:11–18. This trend was also observed in West Virginia. *See id.* at 82:4–9. In West Virginia, heroin mortality began rising in 2010, peaked in 2013, and then began declining. *See id.* at 82:23–83:10.

e. Chief Holbrook testified that, by 2013, heroin had returned and became the number one threat to Huntington. *See* 6/17 Tr. (Holbrook) at 241:17–19.

f. Mr. Brown testified by deposition designation that, by 2015, Appalachia HIDTA recognized that a significant portion of the opioid crisis stems from illegally-trafficked heroin. *See* V. Brown 7/8/20 Dep. Designations at 137:19–138:6.

186. The increase in heroin overdoses corresponded with a change in the nature of heroin drug trafficking, as cartels have developed more efficient distribution channels and made heroin more widely available and easier to purchase at lower cost.

a. Dr. Waller testified that Mexican drug cartels were ready to satisfy the demand of the emerging market for illicit opioids by using new pizza delivery-like ways of marketing heroin to potential suburban buyers who otherwise might have been frightened to engage with the illicit drug trade. This expanded the supply and availability of heroin. *See* 5/4 Tr. (Waller) at 181:7–18, 182:5–7, 220:3–6. Dr. Waller further testified that the relatively low price of heroin and fentanyl compared with prescription opioids contributed to the transition from prescription opioids to heroin and other illicit opioids. *See id.* at 205:13–21.

187. The increase in heroin overdoses is also related to the fact that the supply of heroin into Cabell/Huntington has increased significantly due to extensive illegal drug trafficking activity. This new wave of heroin has the highest purity levels ever seen in the community, and at the lowest price.

a. Dr. Waller testified that the shift from southeast Asian heroin to Mexican heroin facilitated the proliferation of heroin in communities across the United States through well-established drug trafficking organizations and distribution channels that had long been routes for distribution of other illicit drugs such as cannabis and cocaine. *See* 5/4 Tr. (Waller) at 179:6–18.

b. Dr. Gupta testified that the price of heroin has been reduced while the purity of heroin has increased in West Virginia over the last number of years. *See* 5/6 Tr. (Gupta) at 112:4–7.

c. Sheriff Zerkle testified that the heroin available today is different from past heroin: it is available in different forms, is stronger, and has higher purity. *See* 5/27 Tr. (Zerkle) at 178:8–18.

d. Dr. Keyes testified that, in the mid-1990s, the U.S. supply of South American heroin increased substantially while the fraction of the market controlled by the Asian heroin decreased dramatically. *See* 6/14 Tr. (Keyes) at 40:20–41:2. Abundant supply, low price, and high purity of the Colombian heroin reduced the price per gram of pure heroin. *See id.* at 41:13–19.

e. Chief Holbrook testified that heroin became an emerging threat "due to the availability and affordability of the drug." *See* 6/17 Tr. (Holbrook) at 216:23–217:6.

188. Heroin is typically injected rather than ingested in pill form. *See* 5/5 Tr. (Gupta) at 90:25–91:5.

189. Injection drug use involves sharing needles, which may result in sharing infectious diseases like HIV, Hepatitis B, and Hepatitis C. *See* 5/5 Tr. (Gupta) at 90:25–91:5; *see also* 5/6 Tr. (Gupta) at 121:17–122:5; 6/16 Tr. (Yingling) at 148:9–18, 151:3–7 (testifying that the rise in infectious diseases like Hepatitis B, Hepatitis C, and HIV that started around 2014 or 2015 is directly tied to intravenous drug abuse).

190. The risk of infectious diseases like HIV, Hepatitis B, Hepatitis C, and infective endocarditis is associated with injection drug use. *See* 6/17 Tr. (Feinberg) at 161:8–13, 115:2–9, 128:12–13, 135:14–17, 140:7–20.

191. Injection drug use relates only to use of illicit drugs, or non-medical use of licit drugs. *See* 6/17 Tr. (Feinberg) at 162:20–163:2, 166:18–21.

192. Since 2013–2014, there has been a significant increase in the level of illicit fentanyl overdoses in Cabell/Huntington.

a. Dr. Waller testified that there was a marked increase in overdose deaths from illicitly made synthetic opioids, generally related to fentanyl, beginning in 2013. *See* 5/4 Tr. (Waller) at 176:22–177:5.

b. Dr. Gupta testified that fentanyl and fentanyl analogues—alone or in combination—became a significant drug abuse problem beginning in 2014. *See* 5/6 Tr. (Gupta) at 82:11–18. From 2014–2016, the percent of overdose deaths in West Virginia involving fentanyl increased from 9 percent to 41 percent. *See id.* at 100:5–19.

c. Dr. Murphy testified that national fentanyl mortality was relatively flat between 2010 and 2013, and then skyrocketed starting around 2013. *See* 7/8 Tr. (Murphy) at 81:11–18. This trend was also observed in West Virginia. *See id.* at 82:4–9. In West Virginia, fentanyl mortality sharply increased after 2013. *See id.* at 82:23–83:10.

d. Mr. Lemley testified that there was an increase in overdoses at the end of 2016 related to fentanyl, and that fentanyl was a cause of concern in Huntington by the end of that year. *See* 5/21 Tr. (Lemley) at 204:18–25, 216:7–10, 217:10–14, 241:7–11, 241:16–19.

e. Dr. Smith testified that illicit fentanyl manufactured overseas was responsible for the large increase in overdose deaths beginning in 2013. *See* 6/10 Tr. (Smith) at 138:11–139:3, 158:6–16. Illicit fentanyl was involved in at least half of all fatal overdoses in Cabell County in 2016–2018. *See id.* at 202:20–24.

f. Dr. Keyes testified that, starting in 2015, Cabell County experienced an exponential increase in fentanyl overdoses. *See* 6/11 Tr. (Keyes) at 202:7–15.

g. Mr. Brown testified by deposition designation that illicit fentanyl has been a threat in Huntington since at least 2016. *See* V. Brown 7/8/20 Dep. Designations at 148:8–17, 148:19.

193. The fentanyl driving the increase in deaths in West Virginia is illicitly sourced and generally not of pharmaceutical origin. *See* 5/6 Tr. (Gupta) at 83:6-24, 100:20–22; 6/14 Tr. (Keyes) at 43:13-25; 7/8 Tr. (Murphy) at 80:17–23, 83:23–84:3.

194. The increase in fentanyl overdoes is related to the fact that illicit fentanyl is substantially more potent than heroin. Drug dealers adulterate heroin with illicit fentanyl (often without the user's knowledge) because fentanyl is cheaper, more potent, and easier to transport than heroin.

a. Dr. Waller testified that fentanyl is approximately 80 times more potent than heroin. *See* 5/4 Tr. (Waller) at 177:20–178:2.

b. Mr. Lemley testified that the increase in the prevalence of fentanyl in Cabell/Huntington is due in part to the increased potency and lower price of fentanyl. *See* 5/21 Tr. (Lemley) at 204:10–13. Fentanyl is significantly more potent than heroin, but cheaper than both heroin and marijuana. *See id.* at 203:22–204:4, 204:10–13.

c. Dr. Keyes testified that fentanyl is cheaper to produce than heroin; the wholesale price is one-tenth of heroin's price by weight, and is 30 to 40 times stronger than heroin, so that a comparable dose of fentanyl would be 1/300 to 1/400 of the wholesale price of heroin. *See* 6/14 Tr. (Keyes) at 42:3–11.

d. Dr. Feinberg testified that polysubstance drug abuse that involves fentanyl is common in West Virginia at present because "fentanyl is in almost everything." *See* 6/17 Tr. (Feinberg) at 176:22–177:7.

e. Dr. Murphy testified that fentanyl represents a cheap way for drug dealers to lower their costs by adulterating heroin. *See* 7/8 Tr. (Murphy) at 100:4–12.

195. Fentanyl has affected the Eastern United States much more than the Western United States. The reason for this disparity lies in differences in the illegal drug supply in those two geographic regions.

a. Dr. Waller testified that it is easier to mix fentanyl with powder heroin, which is predominant in the Eastern United States, than with black tar heroin, which is predominant in the Western United States. *See* 5/4 Tr. (Waller) at 189:20–190:25.

b. Dr. Keyes testified that Mexican black tar heroin dominated the West Coast market while Colombian white powder heroin dominated the East Coast. *See* 6/14 Tr. (Keyes) at 41:3–12.

c. Dr. Murphy testified that:

i. There was a divergence in heroin and fentanyl mortality between the Western and Eastern states in the post-2010 period. *See* 7/8 Tr. (Murphy) at 100:13–101:3.

ii. The increased opioid mortality seen in Eastern states after 2010 is explained by differences in the heroin supply compared to the Western states. *See* 7/8 Tr. (Murphy) at 98:4–13.

iii. The Western U.S. has traditionally been supplied with black tar heroin, which originates primarily from Mexico and is much harder to adulterate with fentanyl. *See* 7/8 Tr. (Murphy) at 98:4–13, 99:18–100:3.

iv. The Eastern U.S. has much more powdered heroin, which originates primarily from Colombia and is easier to adulterate with fentanyl. *See* 7/8 Tr. (Murphy) at 98:4–13, 99:18–100:12.

v. The expansion of fentanyl has been much greater in the Eastern U.S. than the Western U.S. since 2010. *See* 7/8 Tr. (Murphy) at 98:14–99:11.

vi. Fentanyl mortality has risen much faster in the Eastern U.S. due to the nature of the supply chain in the illicit market. *See* 7/8 Tr. (Murphy) at 99:12–17.

196. Criminal actors are responsible for determining the volume of supply, price, and purity of the illegal drugs sold in Cabell/Huntington. Defendants play no role in making those determinations. *See, e.g.*, 5/4 Tr. (Waller) at 220:19–221:11; 7/8 Tr. (Murphy) at 101:12–17; D. Cox 7/15/20 Dep. Designations at 176:19–20, 177:1–2, 177:19–178:7, 179:5–8, 179:12, 179:14–17, 179:22, 180:2–5, 180:9.

XII. Plaintiffs' Claim of a "Gateway" Between Prescription Opioid Misuse and Heroin/Fentanyl Abuse

197. Plaintiffs allege that prescription opioid abuse caused individuals in Cabell/Huntington to turn to the use and abuse of heroin and illicit fentanyl, and that rates of heroin/fentanyl abuse would be substantially lower if Defendants had distributed fewer prescription opioids. *See, e.g.*, Pls.' Mem. of Law in Opposition to Defs.' Mots. for Judgment on Partial Findings on Causation (ECF No. 1469) at 20–21.

198. No matter whether Plaintiffs' theory is correct, the alleged progression from prescription opioid abuse to the abuse of heroin and illicit fentanyl would not have occurred in the same way without a significant increase in prescribing of opioids by doctors and without a significant increase in the misuse and abuse of prescription opioids as an alleged precursor to heroin/fentanyl abuse. *See supra* Findings ¶¶ 43–44, 100–102, 111–114.

199. The available data indicates that non-medical prescription opioid use (*i.e.*, opioid misuse) is neither necessary nor sufficient for the initiation of heroin use and that other factors contribute to the increase in the rate of heroin use and related mortality. See 6/15 Tr. (Keyes) at 15:2-22.

200. Epidemiological studies have found that most persons who misuse prescription opioids do not subsequently turn to heroin use.

a. Dr. Keyes testified that the vast majority of people who misuse prescription opioids do not progress to heroin use. *See* 6/14 Tr. (Keyes) at 193:4-7. Dr. Keyes further testified that "[t]he absolute risk of transitioning to heroin, given prescription opioid use, is relatively small." *See id.* at 195:19–196:2.

b. A study by Pradip K. Muhuri and colleagues entitled "Associations of Non-medical Pain Reliever Use and Initiation of Heroin Use in the United States"—which Dr. Keyes relied on in forming her opinions, *see* 6/14 Tr. (Keyes) at 188:25–189:8—found that only 3.6% of people who misuse prescription opioids initiated heroin within the five-year period following their first misuse of prescription opioids, *see id.* at 193:18-25.

c. The Muhuri study found that 96.4% of people who misused prescription opioids did not use heroin within five years of their first misuse of prescription opioids. *See* 6/14 Tr. (Keyes) at 194:1–5.

201. In recent years, there has been an increase in heroin use as the first use of an opioid.

a. A study by Theodore Cicero and colleagues entitled "Increased Use of Heroin as an Initiating Opioid of Abuse: Further Considerations and Policy Implications," found that heroin use as a first opioid grew sharply from 8.7% of the sample in 2005 to almost 31.6% in 2015. *See* 6/14 Tr. (Keyes) at 213:12–214:13.

b. Dr. Keyes testified that she does not know whether the percentage of heroin users who started with heroin as their first opioid has increased since 2015. *See* 6/14 Tr. (Keyes) at 217:14–17.

c. Dr. Waller testified that, since 2010, drug abusers are increasingly likely to report that heroin was their first opioid misuse. *See* 5/4 Tr. (Waller) at 179:19–180:17.

202. Shifts in the heroin market played a role in increasing the risks of transition to heroin use among people with a dependence on prescription opioids. *See* 6/14 Tr. (Keyes) at 40:9–19.

203. The epidemiological studies that Plaintiffs reply upon "are mostly observational and descriptive, *i.e.*, non-experimental." *See* 6/15 Tr. (Keyes) at 12:9–20.

204. The epidemiological studies that Plaintiffs rely upon evaluate the relationship between ***misuse*** or ***non-medical use*** of prescription opioids and later heroin use.

a. In her expert report, Dr. Keyes wrote that she "reviewed 16 studies that found that individuals who use prescription opioids non-medically have higher rates of injecting and snorting heroin than individuals who do not use prescription opioids." 6/14 Tr. (Keyes) at 200:23–201:10.

205. Dr. Wilson Compton—the Deputy Director of NIDA—reviewed 14 of the 16 epidemiological studies that Dr. Keyes relied on and published an article in the New England Journal of Medicine in 2016 stating that "conclusions about cause and effect

[between non-medical prescription opioid use and heroin use] are uncertain." *See* 6/15 Tr. (Keyes) at 10:5–15, 11:15–18, 11:23–12:4, 12:5–8, 12:21–13:2, 14:2–20.

206. The epidemiological literature finds that individuals who misuse prescription opioids before turning to heroin also abuse other substances before or at the same time as their misuse of prescription opioids.

a. Dr. Keyes testified that, among heroin users, the most common first substance use is tobacco and alcohol. 6/14 Tr. (Keyes) at 236:17–24. Dr. Keyes further testified that a majority of heroin users started using marijuana or cocaine or other illegal drugs before turning to heroin. *See id.* at 237:5–9.

b. The Muhuri study that Dr. Keyes relied on found that all heroin users who had previously misused prescription opioids had also previously used illicit non-opioid drugs. *See* 6/14 Tr. (Keyes) at 234:15–235:9.

c. The Muhuri study that Dr. Keyes relied on found that nearly all of the heroin users that had not previously misused prescription opioids had previously used illicit non-opioid drugs. *See* 6/14 Tr. (Keyes) at 235:21–236:1.

d. The Muhuri study that Dr. Keyes relied on found that 98.9% of heroin users had previously used illegal drugs such as marijuana, hashish, cocaine, crack, hallucinogens, and inhalants. *See* 6/14 Tr. (Keyes) at 236:2–6.

207. The evidence reflects that people who abuse drugs are prone to abuse many drugs.

a. Dr. Murphy testified that some people are prone to abuse drugs and will abuse whatever substance is available, and often different ones. *See* 7/8 Tr. (Murphy) 144:12–25.

b. Dr. Waller testified that all addictive substances have the same "final common pathway" in the brain: they all affect dopamine. *See* 5/4 Tr. (Waller) 69:12–15.

c. Dr. Feinberg testified that drug addiction is a polysubstance issue, and the real problem of addiction lies in the "social and economic fabric." *See* 6/17 Tr. (Feinberg) 181:2–9.

d. Ms. Colston explained that the country is suffering not from an opioid epidemic but from a crisis of polysubstance abuse and substance use disorder. *See* 7/12 Tr. (Colston) 146:18–24.

208. The overwhelming majority of drug overdoses in West Virginia involve more than one drug, indicating that substance users are engaging in polysubstance abuse.

a. Mr. Lemley testified that there is typically more than one drug in an overdose victim's system when they die. *See* 5/21 Tr. (Lemley) at 231:1–6.

b. Dr. Gupta testified that the overdose victims included in historical overview report from 2011–2015 had an average of at least 2.3 controlled substances in their bodies at the time of death. *See* 5/5 Tr. (Gupta) at 74:14–21; Ex. P-41213 (West Virginia Drug Overdose Deaths Historical Overview) at .00004. Dr. Gupta further testified that the 2016 overdose fatality analysis found that 86% of overdose victims in 2016 had multiple drugs in their system at the time of death. *See id.* at 180:7–12; Ex. P-44211 (2016 West Virginia Overdose Fatality Analysis) at .00013.

c. Dr. Gupta testified that most drug overdose deaths involve multiple substances, meaning an individual death may involve multiple types of drugs. *See* 5/6 Tr. (Gupta) at 116:10–19.

d. Dr. Smith testified that polypharmacy is common in drug overdose deaths in Cabell/Huntington. *See* 6/10 Tr. (Smith) at 133:13–25, 153:23–154:8. Dr. Smith further testified that over three quarters of all fatal overdoses from 2005 to 2017 in West Virginia involved multiple drugs. *See id.* at 161:20–162:1.

e. Dr. Keyes testified that there are many polydrug overdoses in Cabell/Huntington, meaning overdoses where multiple drugs are found in somebody's body at the time of death. *See* 6/14 Tr. (Keyes) at 116:1–4.

209. The evidence does not support a connection between present-day opioid mortality and prescription opioid shipments in the pre-2010 period. *See* 7/8 Tr. (Murphy) at 84:25–85:6.

210. The evidence does not support the conclusion that there is a transition from prescription opioids to illegal drugs. *See* 7/8 Tr. (Murphy) at 103:1–8.

211. There is not a relationship between prescription opioid shipments from 1997 to 2010 and heroin/fentanyl mortality after 2010. *See* 7/8 Tr. (Murphy) at 90:5–12.

a. Less than 3% of the variation in mortality associated with heroin and fentanyl after 2010 is explained by prescription opioid shipments from 1997 to 2010. *See* 7/8 Tr. (Murphy) at 88:2–89:16. This is a very weak, statistically insignificant association, and is no greater than what one would expect to see by chance. *Id.* at 88:2–21, 90:2–4.

b. Overwhelmingly, the variation in heroin and fentanyl mortality after 2010 is explained by factors other than prescription opioid shipments from 1997 to 2010. *See* 7/8 Tr. (Murphy) at 89:17–20, 90:5–12.

212. There are significant age and gender differences between the population of people who were receiving prescription opioids from 2001–2010 and those who overdosed from heroin and fentanyl after 2010.

a. Older people who were receiving more prescription opioids from 2001-2010 are underrepresented in the national heroin and fentanyl mortality data. *See* 7/8 Tr. (Murphy) at 91:2–24.

b. The age and gender differences between prescription opioid shipments and heroin and fentanyl mortality observed at the national level are similar to those observed in West Virginia. 7/8 Tr. (Murphy) at 92:14–23.

c. The age and gender differences between pre-2010 prescription opioid shipments and post-2010 heroin and fentanyl mortality do not support the conclusion that the people who were prescribed opioids prior to 2010 shifted over to consuming illicit opioids. 7/8 Tr. (Murphy) at 92:24–93:12.

d. Heroin and fentanyl overdose deaths after 2010 are skewed much more towards younger ages as compared to prescription opioid mortality prior to 2010. 7/8 Tr. (Murphy) at 95:4–25.

213. Variations in fentanyl mortality between the Eastern and Western states are explained by differences in the illegal drug supply. *See supra* Findings ¶ 195.

214. Any transition from prescription opioids to heroin involves criminal conduct, including by (1) the criminals responsible for manufacturing the illegal drugs, (2) the criminals responsible for trafficking the illegal drugs, and (3) the end-user who possesses and uses the illegal drugs. *See* 6/14 Tr. (Keyes) at 205:9–20, 206:11–15.

215. A number of factors stand between Defendants' distribution of prescription opioids to pharmacies and the subsequent abuse of heroin, including the following:

a. A doctor prescribes opioids. *See supra* Findings ¶¶ 8, 40–43.

b. A pharmacy dispenses those opioids pursuant to a prescription. *See supra* Findings ¶¶ 50–51.

c. The opioids are subsequently diverted to misuse by the patient or a third party. *See supra* Findings ¶¶ 103–104, 113–114, 115.

d. The person engaged in misuse or abuse of prescription opioids may also obtain illegally trafficked or counterfeit prescription opioids that were not distributed by Defendants or any other wholesale distributor. *See supra* Findings ¶¶ 173–175.

e. Heroin is illegally trafficked into Cabell/Huntington. *See supra* Findings ¶¶ 177–178.

f. A person engaged in misuse of prescription opioids obtains illegal heroin from a criminal drug trafficker or street dealer. *See supra* Findings ¶¶ 177–178, 186–187, 196.

g. That person then abuses heroin.

216. A fentanyl overdose following the use of heroin involves further illegal acts, which include a drug trafficker who brings fentanyl into the community and a drug dealer who adulterates heroin with fentanyl. *See supra* Findings ¶¶ 177–178, 192–196.

XIII. Other Contributing Causes

217. Numerous third-party actors, through their wholly independent actions, contributed more directly than Defendants to the opioid crisis in Cabell/Huntington and any corresponding harms suffered by Plaintiffs.

218. Those actors include the following:

a. Manufacturers of prescription opioids, which developed the medicines and, according to Plaintiffs' own allegations, deceptively marketed the medications, thereby causing some doctors acting in good faith to over-prescribe opioids. *See supra* Findings ¶¶ 11–13, 25.

b. Licensed doctors who, in the good-faith exercise of their professional judgment, and pursuant to the prevailing standard of care, prescribed opioids for the treatment of pain, and thereby increased the volume of prescription opioids prescribed to patients in Cabell/Huntington. *See supra* Findings ¶¶ 8, 40–45, 51.

c. Licensed pharmacists and other dispensers who, in the good-faith exercise of their professional judgment, dispensed opioids pursuant to legitimate prescriptions written by doctors, and thereby increased the volume of prescription opioids dispensed to patients in Cabell/Huntington. *See supra* Findings ¶¶ 10, 48–49, 51.

d. FDA, which approved every prescription opioid that Defendants distributed as safe and effective for their intended use, and thereby authorized the supply of these medicines in Cabell/Huntington. *See supra* Findings ¶¶ 20, 97.

e. DEA, which

i. increased the annual quotas for the manufacture of prescription opioids almost every year from 1993 to 2015 based on a determination that the quota was needed to meet legitimate medical needs, *see supra* Findings ¶ 72;

ii. expressly endorsed the prescribing guidelines promulgated by the FSMB (of which the West Virginia Board of Medicine is a member), which approved the use of prescription opioids to treat chronic pain, *see supra* Findings ¶ 26(d);

iii. advised Congress and the public that more than 99% of doctors were prescribing opioids for legitimate medical reasons, *see supra* Findings ¶ 45(d)–(e);

iv. was aware quarter-by-quarter and year-by-year of the total volume of prescription opioids delivered to Cabell/Huntington, as well as the total volume delivered to each pharmacy in Cabell/Huntington, *see supra* Findings ¶¶ 80–81; and

v. thereby contributed to the increases in the supply of prescription opioids in Cabell/Huntington, and had full knowledge of those increases through the ARCOS database, *see supra* Findings ¶¶ 80–81, 85.

f. The West Virginia Board of Medicine, which

i. approved the FSMB's guidelines for prescribing opioids, *see supra* Findings ¶ 26(d);

ii. issued guidelines to doctors in 1997, 2005 and 2013 that affirmatively encouraged the use of prescription opioids for the treatment of pain, and highlighted the importance of effective pain treatment by doctors in West Virginia, *see supra* Findings ¶ 27;

iii. sent to every West Virginia doctor *Responsible Opioid Prescribing* (authored by Dr. Scott Fishman), which recommended the use of prescription opioids for the long-term treatment of chronic pain, *see supra* Findings ¶¶ 22(f)–(g), 27(d)–(e); and

iv. through the statewide PDMP database,[7] had all the information needed to detect doctors who were over-prescribing or illegally prescribing opioids (including "pill-mill" doctors), yet rarely investigated such doctors and even more rarely acted to suspend or revoke their licenses to practice medicine, *see* 7/7 Tr. (Hughes) at 214:19–242:17.

g. The Joint Commission, whose pain management standards Huntington claimed "led to a sharp increase in prescriptions for opioids" and were a "significant contributor to the over-prescription of opioids." Ex. DEF-WV-02124 (Joint Commission Complaint) ¶¶ 30, 81; *see also supra* Findings ¶ 24.

h. Health insurers, such as the West Virginia Bureau for Medical Services and West Virginia Public Employees Insurance Agency, which had unique access to claims data and other information that would have allowed them to identify problematic patients and prescribers in Cabell/Huntington, which reimbursed for massive quantities of opioids and failed to restrict coverage for many opioids, which failed to timely implement many of the prescription management tools available to them, and which discouraged the use of alternative pain treatments by means of coverage restrictions. *See supra* Findings ¶¶ 54–63.

[7] The West Virginia Board of Pharmacy operates the prescription drug monitoring program ("PDMP"), also referred to as the West Virginia Controlled Substances Monitoring Program. The Program collects data concerning the prescribing and dispensing of all Schedule II-IV controlled substances in West Virginia. Distributors do not have access to the West Virginia Controlled Substances Monitoring Program. *See* 7/7 Tr. (Hughes) at 214:19–242:17.

i. Drug traffickers who illegally distributed diverted prescription opioids to individuals in Cabell/Huntington. *See supra* Findings ¶¶ 169, 171–173.

j. Individuals who deliberately or inadvertently diverted prescription opioids (*e.g.*, by selling, stealing, or giving away those medicines). *See supra* Findings ¶¶ 103, 113, 115.

k. Individuals who used diverted prescription opioids in the absence of a prescription or legitimate medical need. *See supra* Findings ¶¶ 115.

l. Illegal drug traffickers who distributed heroin and illicit fentanyl in Cabell/Huntington. *See supra* Findings ¶¶ 177–178.

m. Individuals who used illegal opioids like heroin and illicit fentanyl. *See supra* Findings ¶¶ 176.

XIV. Plaintiffs' Proposed Equitable Remedy

A. Overview of the Proposed Abatement Plan

219. Plaintiffs propose a 15-year "Abatement Plan" as their equitable remedy. Plaintiffs' expert Dr. Alexander developed the plan, *see* 6/28 Tr. (Alexander) at 16:19–17:1, with inputs from Plaintiffs' experts Dr. Young, *see* 6/16 Tr. (Young) at 104:6–10, and Dr. Keyes, *see* 6/28 Tr. (Alexander) at 148:23–149:1. Plaintiffs' expert Mr. Barrett testified that the total cost of the plan over 15 years (in future dollars) is $2,544,446,548. *See* 6/29 Tr. (Barrett) at 106:8–12.

220. The Abatement Plan consists of four categories of programs that Dr. Alexander testified are needed to address the opioid epidemic in Cabell/Huntington. *See* 6/28 Tr. (Alexander) at 36:2–7.

a. "Category 1: Prevention" consists of six elements: (1) health professional education, (2) patient and public education, (3) safe storage and drug disposal, (4) community prevention and resiliency, (5) harm reduction, and (6) surveillance, evaluation, and leadership. *See* 6/28 Tr. (Alexander) at 37:4–38:19. The total cost of this category is $48,720,554 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 106:19–107:10.

b. "Category 2 — Treatment" consists of direct medical treatment and other related services for people with Opioid Use Disorder ("OUD").[8] *See* 6/28 Tr. (Alexander) at 46:23–47:5, 137:19–141:13. Dr. Alexander characterized many of these programs as "treat[ing] some of the collateral or downstream harms that have occurred because of addiction." 6/28 Tr. (Alexander) at 46:23–47:5. The total cost

[8] Opioid Use Disorder, or OUD, is the dysfunctional use of opioids where the person has lost control over use of the substance, experiences negative social impacts, and causes harm to the person. *See* 5/4 Tr. (Waller) at 52:8–21, 53:10–54:2.

of this category is $2,050,815,634 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 107:11–20.

c. "Category 3 – Recovery" includes programs to address downstream needs and harms created by opioid abuse and addiction, including (1) expansion of police capabilities, (2) expansion of drug-related capabilities in the justice system, (3) creating and encouraging employment opportunities for people with OUD, and (4) expanding mental health services and grief support for people affected by OUD. *See* 6/28 Tr. (Alexander) at 141:14–143:9. Dr. Alexander explained that the "recovery" category of his plan includes "programs and services that aren't focused" "directly on treating individuals with active addiction, but nevertheless will allow for those individuals to flourish and for the community as a whole to regain its former livelihood and standing." 6/28 Tr. (Alexander) at 59:14–24. The total cost of this category is $99,238,834 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 107:21–108:16.

d. "Category 4 – Special Populations" is intended to fund services and programs for populations adversely affected by opioid addiction and abuse, including services for (1) pregnant woman with OUD and babies with neonatal abstinence syndrome, (2) children and families affected by OUD, (3) homeless or housing insecure individuals affected by OUD, and (4) individuals who misuse opioids. *See* 6/28 Tr. (Alexander) at 143:16–145:8. As Dr. Alexander explained, the "special populations" category includes "direct treatment" and "wrap-around services" for special populations such as pregnant women, women with children, families, and incarcerated people. 6/28 Tr. (Alexander) at 64:5–17. The total cost of this category is $345,671,523 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 108:17–109:12.

B. The Proposed Abatement Plan Addresses Harms Caused by Opioid Abuse and Addiction, and Not Defendants' Conduct.

221. Virtually the entirety of the proposed Abatement Plan is addressed to programs and services to treat opioid addiction and abuse, and the attendant harms caused by opioid abuse and addiction. *See* 6/28 Tr. (Alexander) at 29:5–23.

a. Three of the four categories of the Abatement Plan, Categories 2 through 4, consist entirely of programs directed to addressing the downstream harms and downstream effects caused by opioid addiction and abuse.

vii. Category 2 is for direct medical treatment and related services for people with OUD. *See* 6/28 Tr. (Alexander) at 46:23–47:5, 137:17–141:13.

viii. Category 3 is for programs needed to address needs created by a population of people with OUD. *See* 6/28 Tr. (Alexander) at 141:14–143:9.

ix. Category 4 is for "special populations that are adversely affected by opioid use and misuse and by OUD." 6/28 Tr. (Alexander) at 143:10–15.

b. Category 1 of the Abatement Plan also includes programs addressed to drug abuse and addiction – the subcategory of "Harm Reduction" within Category 1 provides services for intravenous drug users, including syringe exchanges, screening for blood-borne disease, and fentanyl testing for illegal opioids. *See* 6/28 Tr. (Alexander) at 135:12–25. This accounts for $19,554,622 (in future dollars) of the Abatement Plan. *See* 6/29 Tr. (Barrett) at 107:7–8, 110:10.

c. In total, Categories 2 through 4, plus Harm Reduction within Category 1, account for $2,515,280,613 (in future dollars), *see* 6/29 Tr. (Barrett) at 107:7–8, 107:11–20, 107:21–108:16, 108:17–109:12, 110:10, representing 98.85% of the total costs of the Abatement Plan.

222. Only one element of the Abatement Plan addresses the volume of prescription opioids in Cabell/Huntington and is arguably tailored to Defendants' allegedly wrongful conduct.

a. Category 1 includes a program for "Safe Storage and Drug Disposal," which entails collection sites for unused pills that could remove excess prescription opioids from the community. *See* 6/28 Tr. (Alexander) at 133:11–14.

b. The "Safe Storage and Drug Disposal" program accounts for $35,972 (in future dollars over 15 years), *see* 6/29 Tr. (Barrett) at 107:3–4, 110:8, representing 0.0014% of the total costs of the Abatement Plan.

223. Category 1 of the Abatement Plan includes several educational and information-collection programs that do not address the volume of prescription opioids distributed in the Cabell/Huntington Community.

a. "Health Professional Education" involves educating prescribers about prescribing opioids and treating OUD. *See* 6/28 Tr. (Alexander) at 130:10–22. This accounts for $5,437,224 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 106:19–25, 110:6.

b. "Patient and Public Education" consists of educating the public about the risks of legal and illegal opioid use. *See* 6/28 Tr. (Alexander) at 37:13–19. This accounts for $538,834 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 107:1–2, 110:7.

c. "Community Prevention and Resiliency" provides "the community a central gathering space, a space for educational programming." *See* 6/28 Tr. (Alexander) at 37:25–38:5. This accounts for $17,924,519 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 107:5–6, 110:9.

d. "Surveillance, Evaluation, and Leadership" involves the collection of data on the opioid epidemic and is the "mission control to this plan." 6/28 Tr. (Alexander) at 38:12–19, 136:11–16. This accounts for $5,229,383 in future dollars over 15 years. *See* 6/29 Tr. (Barrett) at 107:9–10, 110:11.

224. The Abatement Plan does not include any provisions to constrain Defendants' conduct generally or their distribution of prescription opioids in Cabell/Huntington specifically. Dr. Alexander admitted that the Abatement Plan (1) "does not recommend any new licensing requirements for distributors," (2) "does not propose any new reporting requirements for distributors," and (3) "does not propose any new physical security requirements for distributors." 6/28 Tr. (Alexander) at 123:19–22, 124:7–17, 124:19–22.

225. Dr. Alexander testified that the Abatement Plan is intended to address the opioid epidemic as a whole, *see* 6/28 Tr. (Alexander) at 29:16–23, and is not limited to addressing prescription opioids. *See* 6/28 Tr. (Alexander) at 121:2–10.

C. The Abatement Plan Takes No Account of the Many Opioid-Related Programs and Services Already Being Provided in Cabell/Huntington.

226. The Abatement Plan does not attempt to determine the unmet need for OUD treatment programs or other opioid-related services in Cabell/Huntington, and does not take account of the current programs in the community or their capacity to provide the services called for by the Abatement Plan. *See* 7/12 Tr. (Colston) at 140:21–141:2, 142:2–5.

a. In devising the Abatement Plan, Dr. Alexander did not "subtract out the level of services that are currently being provided in the City of Huntington and Cabell County." 6/28 Tr. (Alexander) at 96:18–22; *see also id.* at 97:5–7. Dr. Alexander offered no opinions on the current capacity of the opioid-related programs already being offered in the community or the incremental needs of those programs. *See id.* at 55:3–57:10; 106:5–107:24.

b. The Abatement Plan does not include a needs assessment of the existing opioid-related programs in Cabell/Huntington, *see* 7/12 Tr. (Colston) at 137:9–22, does not address the existing capacity and availability of opioid-related programs in Cabell/Huntington, *see id.* at 138:12–15, and does not assess the number of people already served by such opioid-related programs in Cabell/Huntington, *see id.* at 138:16–21, 139:7–1439:23.

c. Dr. Alexander conceded that many of the elements of the proposed Abatement Plan are already in place in some form in Cabell/Huntington. *See, e.g.*, 6/28 Tr. (Alexander) at 130:23–131:4 (agreeing that the West Virginia State Board of Medicine engages in continuing medical education, including continuing education on opioid prescribing); *id*. at 132:22–133:6 (agreeing that the CDC implemented a mass media campaign on the risks and benefits of opioids in West Virginia); *id.* at 133:15–23 (agreeing that there are already multiple pill collection sites in Cabell/Huntington); *id*. at 134:18–24 (agreeing that there are resiliency efforts and community building efforts already underway in Cabell and Huntington); *id*. at 136:17–24 (agreeing that evaluation, surveillance and leadership is currently being provided in Cabell County and Huntington); *id*. at 141:1–9 (agreeing that the community has already been involved in extensive efforts to distribute naloxone).

d. Dr. Young did not evaluate the capacity of existing programs in Cabell and Huntington. *See* 6/16 Tr. (Young) at 83:2–6, 89:2–6. Accordingly, Dr. Young provided no opinion as to the capacity of the programs operating in Huntington and Cabell County, including whether they are at capacity or have available capacity, *see id.* at 129:14–21, or whether they already provide sufficient services for the opioid-related programs called for in the Abatement Plan, *see id.* at 82:13–17.

e. Mr. Barrett did not evaluate whether any of the programs included in the Abatement Plan were already being provided in the community, *see* 6/29 Tr. (Barrett) at 157:4–8, and did not adjust his cost calculations to take account of capacity provided by existing opioid-related programs in Cabell/Huntington. *See id.* at 156:23–157:1, 157:9–14, 158:20–24.

f. Mr. Barrett testified that he "did not look at whether the existing treatment capacity in Cabell-Huntington could encompass treatment of 3,000 people with OUD" because "[w]hether or not the healthcare facilities have the capability of providing that level of care is really not something that I was asked to calculate and that the redress model doesn't identify." 6/29 Tr. (Barrett) at 160:4–12.

g. Mr. Barrett did not know whether, if at all, the Abatement Plan takes existing programs in the community into account. *See* 6/29 Tr. (Barrett) at 156:18–22.

227. It is necessary to understand the current opioid-related programs in a community, and their capacity, before it is possible to evaluate the needs for additional opioid-related programs. *See* 7/12 Tr. (Colston) at 138:22–25.

228. Many programs and services are already being offered in the Cabell/Huntington community to combat the opioid crisis. The programs being offered currently in Cabell/Huntington cover the full spectrum of services needed to address the opioid crisis. *See* 7/12 Tr. (Colston) at 141:7–11.

a. The Great Rivers Regional System for Addiction Care, which is a coalition led by Marshall Health, *see* 6/7 Tr. (O'Connell) at 100:4–9; 100:25–101:5, identified six components for an effective opioid response plan. *See id.* at 102:24–103:4. The Great Rivers Regional System found that all six components were already in place in Cabell County as of February 2019. *See id.* at 103:14–20.

b. At least 14 facilities are currently providing medication-assisted treatment for opioid addiction in Cabell County, *see* 6/7 Tr. (O'Connell) at 103:25–104:2, including Ohio Valley Physicians, *see id.* at 114:5–10, Huntington Behavioral Health, *see id.* at 114:5–10, the Methadone Clinic, *see id.* at 114:5–10, and Valley Health, *see id.* at 114:11–15.

c. The City of Solutions is a comprehensive report that documents the extensive range of programs being offered in Cabell/Huntington to address the opioid crisis. *See* 5/28 Tr. (O'Connell) 13:12–15:17. This includes:

i. The "Provider Response Organization for Addiction Care and Treatment" ("PROACT"), which provides OUD treatment services, including "individual group family therapy, non-medication based treatment, medication-based treatment, psychiatric services, pharmacological services, and … peer-based services" in Cabell/Huntington. *See* 5/27 Tr. (O'Connell) at 215:15–25; 6/7 Tr. (O'Connell) at 33:8–18, 35:9–22. PROACT provides comprehensive intake and treatment, including medication-assisted treatment. *See* 6/7 Tr. (O'Connell) at 34:7–8, 34:16–20, 36:5–12. PROACT also offers job placement services. *See* 5/27 Tr. (O'Connell) at 216:12–14. PROACT has the capacity to treat between 547 to 700 individuals at any one time. *See* 5/27 Tr. (O'Connell) at 216:15–16; 6/7 Tr. (O'Connell) at 51:5–21.

ii. Prestera, a program that provides treatment for people with substance use disorder, including withdrawal management and detox, outpatient treatment and medically assisted treatment (or "MAT")[9] in Cabell/Huntington. *See* 6/7 Tr. (O'Connell) at 79:12–24, 80:6–7, 80:21–23. Prestera serves about 20,000 people across West Virginia each year. *See* 6/7 Tr. (O'Connell) at 82:1–3.

iii. Recovery Point, a program that provides peer recovery services to help people with substance use disorder detox from their substance. *See* 6/7 Tr. (O'Connell) at 93:18–94:17. Recovery Point can serve 110 people at a time, *see id.* at 95:3–6, and 68% of people who complete Recovery Point's program maintain sobriety, *see id.* at 96:24–97:5.

iv. The Maternal Addiction Recovery Center ("MARC"), a program run by Marshall Health that provides services, including addiction treatment and medication-assisted treatment, for pregnant women with addiction in Huntington and Cabell County. *See* 5/27 Tr. (O'Connell) at 219:9–22; 6/7 Tr. (O'Connell) at 69:18–70:20.

v. MOMS, a program run by Cabell-Huntington Hospital that provides addiction treatment, including medication-assisted treatment, for post-partum mothers with addiction in Cabell/Huntington. *See* 5/27 Tr. (O'Connell) at 220:7–23; 6/7 Tr. (O'Connell) at 75:18–25, 76:9–20, 77:2–3. MOMS can provide treatment to at least 60 post-partum women at one time. *See* 6/7 Tr. (O'Connell) at 77:16–21.

vi. Lily's Place, which provides care for infants with neonatal abstinence syndrome in a non-hospital setting. *See* 5/27 Tr. (O'Connell) at 227:12–22; 6/7 Tr. (O'Connell) at 83:3–7.

[9] MAT involves treating OUD through the use of medications, such as methadone or buprenorphine. Dr. Waller testified that MAT is a key treatment option for OUD. *See* 5/4 Tr. (Waller) at 210:19–212:2.

vii. Project Hope, a program that provides residential treatment and housing for mothers with substance use disorder. *See* 5/27 Tr. (O'Connell) at 224:3–25; 6/7 Tr. (O'Connell) at 86:17–23. The program has 17 apartments for women and their families. *See* 5/27 Tr. (O'Connell) at 224:21–22. The women stay and receive 24-hour care for up to 6 months. *See* 5/27 Tr. (O'Connell) at 225:15–18.

viii. Hope House, a supportive living program for women who finish Project Hope. *See* 5/27 Tr. (O'Connell) at 226:1–25.

ix. Project Engage, a program that identifies patients who come in for other health issues who might have addiction, and refers them to treatment. *See* 5/27 Tr. (O'Connell) at 220:24–221:21. Project Engage is run by St. Mary's Hospital and the Cabell Huntington Hospital. *See* 6/7 Tr. (O'Connell) at 99:7–22.

x. The Neonatal Abstinence Unit at Cabell-Huntington Hospital, which treats infants born with neonatal abstinence syndrome. *See* 6/7 Tr. (O'Connell) at 29:15–17, 83:16–21.

xi. The Cabell-Huntington Health Department, which runs a harm reduction program that has been "very successful at drawing people out." 5/27 Tr. (O'Connell) at 213:9–14.

xii. CORE, a grant-funded program that provides job training and placement for people recovering from addiction. *See* 5/27 Tr. (O'Connell) at 232:5–13.

d. These are only some of the programs in Cabell/Huntington that address opioid abuse and addiction. *See* 5/28 Tr. (O'Connell) at 13:15–14:25 (testifying that the programs discussed are only those identified in the City of Solutions publication).

D. There Is No Evidence of Unmet Needs in the Cabell/Huntington Community for Opioid-Related Programs and Services Due to a Lack of Funding or Capacity.

229. There is no evidence in the record of any opioid-related services or programs that are not being offered today in the Cabell/Huntington due to lack of funding or capacity.

a. Aside from testimony that the Huntington Quick Response team has limited funds and cannot provide follow-up visits, *see* 5/6 Tr. (Priddy) at 213:24–214:16, no witness testified to any specific opioid-related program or service that is not being offered today in Cabell/Huntington and that would be offered with additional funding.

i. Ms. Priddy testified that the Huntington Quick Response Team requires about $400,000 a year in funding. *See* 5/6 Tr. (Priddy) at 204:4–6.

ii. Dr. Lyn O'Connell described what she felt was "needed" to "mov[e] forward," *see* 5/28 Tr. (O'Connell) at 28:12–32:15, but offered only vague descriptions of "[e]xpanding resources across the community out into the rural areas around our area," *id.* at 30:15–16, and "greater efforts around re-entry services and the linking between incarceration and successful connection," *id.* at 31:6–9, without identifying any specific programs that are not being offered today in Cabell/Huntington due to lack of funding or capacity. Dr. O'Connell mentioned a need for enhanced transportation to support addiction treatment, but two such programs are already in place in Cabell/Huntington, *see id.* at 29:24–30:8. The only other need Dr. O'Connell mentioned was a program for addiction treatment for parenting fathers, but she gave no testimony quantifying the additional funding or capacity needed for such a program. *See id.* at 30:21–25.

iii. Although Sheriff Chuck Zerkle testified that he would "like to expand the Drug Unit more" and that "it don't look good for the county as far as having a ton of money laying around," 5/27 Tr. (Zerkle) at 113:22–114:8, he also testified that the Sheriff's Department does well at current funding levels and has what it needs to do its job. *See id.* at 111:20–24, 182:20–183:3.

b. Plaintiffs presented no evidence that any current opioid-related programs and services in Cabell/Huntington have insufficient capacity to meet the needs of the community.

i. Although several witnesses stated that existing programs need "expansion," *see, e.g.*, 5/7 Tr. (Rader) at 53:6–12, no witness testified to any actual, quantifiable expansion of capacity that is needed for any opioid-related program or service in Cabell/Huntington, or how many people are un-served today by the current levels of opioid-related programs and services in Cabell/Huntington.

ii. Although Chief Rader testified that PROACT is "at capacity," 5/7 Tr. (Rader) at 58:4–10, there are many other treatment programs in Cabell/Huntington beyond PROACT, *see* 6/7 Tr. (O'Connell) at 103:25–104:5, and Sheriff Zerkle testified that Cabell County has sufficient treatment beds to meet demand, *see* 5/27 Tr. (Zerkle) at 97:11–16.

c. Dr. Young did not know, and did not evaluate, whether any of the existing opioid-related programs in Cabell/Huntington currently have a funding deficit. *See* 6/16 Tr. (Young) at 90:21–91:1.

d. Dr. Alexander provided no opinion on the current status of funding for existing opioid-related programs in Cabell/Huntington. *See* 6/28 Tr. (Alexander) at 125:6–12, 125:16–24.

e. Mr. Barrett did not evaluate the funding for existing opioid-related programs in Cabell/Huntington. *See* 6/29 Tr. (Barrett) at 169:5–10.

230. Huntington and Cabell County have excess funds that they are not allocating for any opioid-related programs or services.

a. In 2019, Huntington had $6 million in excess revenue, in 2021 it had $15 million in excess revenue, and it is projected to have $17 million in excess revenue in 2022. *See* 7/12 Tr. (Rufus) at 34:3–22; 6/30 Tr. (Williams) at 137:3–7. Currently, excess funds account for about 25% of the City's total budget. *See* 7/12 Tr. (Rufus) at 35:5–7.

b. The County has excess funds of approximately $600,000. *See* 7/12 Tr. (Rufus) at 35:8–18.

c. The City has not directed any of these excess funds to opioid issues or opioid-related programs. *See* 7/12 Tr. (Rufus) at 33:20–34:2, 35:8–15.

d. Mayor Williams testified that, even with this expected surplus of $17 million, the City is not budgeting any money for opioid treatment. *See* 6/30 Tr. (Williams) at 143:13–144:1.

231. The federal government has allocated extensive funds for opioid-related programs and services that the State of West Virginia has not used and that could be used to pay for opioid-related programs and services in Cabell/Huntington.

a. The State of West Virginia has received significant federal funding to address the opioid crisis, which it has used to coordinate services at the state level to avoid duplication and to completely overhaul West Virginia's treatment system since 2016. *See* 6/16 Tr. (Young) at 126:2–13, 128:4–20, 128:21–129:9.

b. In particular, West Virginia has received approximately $147 million in federal funding for the treatment of substance use disorders, but has only allocated approximately $65 or $66 million. *See* 7/12 Tr. (Colston) at 133:19–25. The State of West Virginia has access to approximately $80 million in unspent federal funds. *See id.* at 134:1–5.

c. The federal government has been increasing federal funding for substance use treatment for years, and the 2022 budget for the federal government increases treatment dollars by over $1 billion, reflecting that funding is likely to continue to be available. *See* 7/12 Tr. (Colston) at 158:23–159:6.

d. The Substance Abuse Prevention and Treatment Block Grant (SABT) provides federal funding of $1.8 billion/year to states for treatment of substance abuse. *See* 7/12 Tr. (Colston) at 81:4–13; 82:7–9.

e. Historically since the 1980s, West Virginia has received approximately $8.4 million a year under the SABT grant, but the most recent allotment for 2021 was $23.1 million. *See* 7/12 Tr. (Colston) at 86:12–19.

f. West Virginia received $5.88 million per year for 2017 and 2018 under the State Targeted Response (STR) Grant. *See* 7/12 Tr. (Colston) at 88:10–20.

g. West Virginia also received an additional $1 million under the STR grant, allocated to states with high rates of opioid overdose. *See* 7/12 Tr. (Colston) at 96:6–13.

h. West Virginia spent only 34.1% of its STR grant by the end of the two-year grant period (2017–2018), leaving 65.9% unspent. *See* 7/12 Tr. (Colston) at 94:6–16.

i. SAMSHA also provided a State Opioid Response (SOR) grant, which began in 2018 and continues to the present. *See* 7/12 Tr. (Colston) at 96:16–22. For 2018 and 2019, West Virginia received $28 million under the SOR grant. *See id.* at 97:25–98:5. For 2020 and 2021, the SOR grant amount was increased to $43 million to be spent over two years. *See id.* at 96:25–97:5.

232. Mayor Williams testified that Huntington does not fund treatment for opioid addiction "because it's already funded from … other sources." 6/30 Tr. (Williams) at 169:1–5. Mayor Williams further testified that these programs "will never be and should never be" funded by Cabell/Huntington. *See id.* at 168:2–9.

233. The evidence shows that the needs of Cabell/Huntington for treatment of opioid addiction are already being met.

a. Dr. Alexander's Abatement Plan estimates that approximately 3,000 people should receive OUD treatment in Huntington and Cabell County each year. *See* 6/28 Tr. (Alexander) at 157:1–3. The costs for OUD treatment are the single largest element of the Abatement Plan. *See* 6/29 Tr. (Barrett) at 107:13–14, 110:15; *see also supra* Findings ¶ 220.

b. Sheriff Zerkle testified that Cabell County has sufficient capacity to meet demand for treatment services for opioid addiction, *see* Tr. 5/27 (Zerkle) at 97:11–16, and that the Cabell/Huntington community has approximately 3,000 treatment beds. *See id.* at 156:4–157:6.

E. The Evidence Shows that the Community Has Already Reached the Goals of the Abatement Plan.

234. Dr. Alexander testified that the Abatement Plan will reduce both overdoses and opioid overdose deaths by 50% over 15 years. *See* 6/28 Tr. (Alexander) at 76:7–11, 97:19–98:6, 171:7–14.

235. The evidence demonstrates those reductions have already occurred over the past three years, and without the investment contemplated by the Abatement Plan.

a. Suspected overdoses decreased by 52% in Cabell/Huntington from 2017 to 2019. *See* 7/12 Tr. (Rufus) at 49:15–23; 5/6 Tr. (Priddy) at 230:4–25 (testifying that overdoses in Cabell/Huntington peaked in 2017 and subsided through 2019,

declining by more than fifty percent); Ex. MC-WV-02098 (CCEMS Drug Overdose Statistics, 2014–2015); Ex. MC-WV-02099 (CCEMS Drug Overdose Statistics, 2016–2017); Ex. MC-WV-02100 (CCEMS Drug Overdose Statistics, 2018–2020); Ex. MC-WV-02101 (CCEMS Drug Overdose Statistics, January–March 2021); 6/30 Tr. (Williams) at 175:17–175:25.

b. Overdose deaths also decreased by 46.7% in Cabell County from 2017 to 2019. *See* 7/12 Tr. (Rufus) at 49: 4–14; 5/6 Tr. (Priddy) at 231:1–3 (fatal overdoses also declined from 2017 to 2018); 6/10 Tr. (Smith) at 203:22–204:16 (overdose fatalities declined from 2017 to 2018); 6/30 Tr. (Williams) at 175:9–16 (overdose deaths "fell substantially" from 2017 to 2019).

236. Although there was an uptick in overdoses for three months in 2020, overdoses have returned to pre-2020 levels and the uptick is attributable to the fall-out from COVID-19.

a. Overdoses spiked in May, June and July of 2020. *See* Ex. MC-WV-02100 at .00002.

b. Ms. Priddy testified that the overdose spike in 2020 occurred after the Huntington Quick Response Team shut down in response to COVID-19. *See* 5/6 Tr. (Priddy) at 210:13–24. Ms. Priddy also testified that overdoses had begun trending downward after the Huntington Quick Response Team began operation in 2017. *See id.* at 209:2–18.

c. Monthly overdose rates in August through December of 2020 and January through March of 2021 (the last provided data) were at or below monthly rates from 2019. *Compare* Ex. MC-WV-02100 at .00002 (stating that there were 89 overdoses in August 2020, 89 in September 2020, 92 in October 2020, 66 in November 2020, and 60 in December 2020) *and* Ex. MC-WV-02101 (stating that there were 81 overdoses in January 2021, 65 in February 2021, and 96 in March 2021) *with* Ex. MC-WV-02100 at .00001 (stating that there were between 40 and 94 monthly overdoses each month of 2019).

237. These downward trends in overdoses and opioid deaths were due to the "comprehensive set of programs that exist in Huntington to address the opioid epidemic." 6/30 Tr. (Williams) at 176:9–12.

238. The Abatement Plan does not take these reductions in overdoses and opioid overdose deaths into account. *See* 7/12 Tr. (Rufus) at 47:25–48:11.

F. The City and County Do Not Pay For or Administer the Overwhelming Majority of Opioid-Related Programs Included in the Plan.

239. Mayor Williams testified that Huntington and Cabell County fund none of the programs described in the City of Solutions. These programs "will never be and should never be" funded by Cabell/Huntington. 6/30 Tr. (Williams) at 168:2–9.

240. The County and City neither administer nor fund the overwhelming majority of programs in Cabell/Huntington addressing opioid abuse and addiction. *See* 7/12 Tr. (Colston) at 141:7–17; 6/30 Tr. (Williams) at 65:21–66:6; B. Thompson (Cabell Cty. 30(b)(6) designee) 7/23/20 Dep. Designations at 40:6–41:1.

241. Mayor Williams testified that he "will not ever expect the city government … to actually start running treatment programs or funding treatment programs" for opioid abuse and addiction. 6/30 Tr. (Williams) at 143:21–144:1.

a. Mayor Williams testified that the city has "never funded opioid treatment." 6/30 Tr. (Williams) at 132:16–18.

b. Mayor Williams also testified that third-party providers also receive grant funding for services, because it has "never been the intention" for Huntington to pay for those substance abuse treatment services. 6/30 Tr. (Williams) at 65:21–66:6, 168:22–24, 168:17–169:5.

242. The Cabell County Commission provided similar testimony in its 30(b)(6) deposition of Cabell County Administrator Beth Thompson.

a. The County testified that it does not provide any addiction treatment, does not provide any funding for programs that provide addiction treatment, and has never considered doing either of those things. *See* B. Thompson (Cabell Cty. 30(b)(6) designee) 7/23/20 Dep. Designations at 133:20-134:7.

243. Neither Cabell County nor Huntington administer or fund programs for the treatment of opioid abuse and addiction or other healthcare programs. *See* 5/27 Tr. (Zerkle) at 156:8–157:17.

a. Dr. O'Connell testified that PROACT is not run or funded by the City or County, *see* 6/7 Tr. (O'Connell) at 36:23–25, 69:15–17; MARC is not run or paid for by the City or County, *see id.* at 74:20–25; MOMS is not run or funded by the City or County, *see id.* at 79:6–11; Prestera is not run by the City or County, *see id.* at 82:16–18; Lily's Place is not run or funded by the City or County, *see id.* at 85:6–16; Project Hope is not run or funded by the City or County, *see id.* at 92:19–24; Recovery Point is not run or funded by the City or County, *see id.* at 97:6–11; Project Engage is not run or funded by the City or County, *see id.* at 99:23–100:3; the Neonatal Treatment Unit is housed at Cabell-Huntington Hospital and supported by Marshall Health physicians, *see id.* at 29:15–17; Ohio Valley Physicians is not run or funded by the City or County, *see id.* at 122:11–19; Huntington Behavioral Health is not run or funded by the City or County, *see id.*; the Methadone Clinic is not run or funded by the City or County, *see id.*; and Valley Health is not run or funded by the City or County, *see id.*

b. Dr. O'Connell also testified that many addiction-related programs are run by Marshall Health. *See* 6/7 Tr. (O'Connell) at 27:9–21. Marshall Health is not part of Huntington or Cabell County, nor is it funded by Huntington or Cabell County. *See id.* at 16:2–4, 16:8–11; 6/16 Tr. (Yingling) at 195:23–196:13.

c. Dr. Werthammer testified that neither Cabell County nor Huntington administer or fund the Neonatal Therapeutic Unit at Cabell Huntington Hospital, Lily's Place, or PROACT. *See* 5/21 Tr. (Werthammer), at 55:6–11, 55: 25–56:7, 57:13–17.

d. Dr. Yingling testified that he was unable to identify any opioid-related programs administered by the Cabell-Huntington Health Department that receive funding from Huntington or Cabell County. *See* 6/16 Tr. (Yingling) at 193:16–194:4.

e. Mr. Barrett testified that Huntington does not provide healthcare services. *See* 6/29 Tr. (Barrett) at 171:16–20.

244. Child welfare, foster care and adoption services are also not run or paid for by Huntington or Cabell County. Instead, they are run and funded by the State of West Virginia. *See* 6/28 Tr. (Alexander) at 144:8–11; 6/29 Tr. (Barrett) at 177:5–17; 6/16 Tr. (Young) at 35:4–6.

245. Programs for the treatment of opioid addiction and other medical services, which comprise the largest elements of the Abatement Plan, are reimbursed by health insurance.

a. Medicaid, Medicare, and other insurance programs pay for opioid-abuse treatment—including medication-assisted treatment, outpatient treatment, and residential treatment—and related medical care for residents in Cabell/Huntington. *See* 6/7 Tr. (O'Connell) at 48:20–49:4, 60:2–5; 5/27 Tr. (Zerkle) at 156:8–157:17 (treatment beds in Cabell County are funded by insurance and state/federal funding).

b. West Virginia Medicaid covers the "entire continuum of substance use disorder services," including psychotherapeutic services, outpatient, inpatient, and physician supervised care. *See* 7/12 Tr. (Colston) at 100:6–21, 115:15–118:1.

c. Medicare also covers both inpatient and outpatient programs for substance use disorder, medication used in treatment other than methadone, and partial hospitalization. *See* 7/12 Tr. (Colston) at 121:1–15. As of January 1, 2020, the opioid treatment program under Medicare Part B also covers methadone, counseling and therapy, and psychotherapy. *See id.* at 121:16–23.

d. The many programs for the treatment of OUD and NAS operating in Huntington and Cabell County receive reimbursement for their services from Medicaid and other insurance.

i. The goal for PROACT is to make all of its services billable to insurance. *See* 6/7 Tr. (O'Connell) at 68:8–10, 68:23–69:1. 67% of PROACT's treatment services have historically been reimbursed by West Virginia Medicaid. *See id.* at 49:5–12. Private insurance, Medicare, and Kentucky and Ohio Medicaid cover an additional 23% combined. *See id.* at 49:13–25.

ii. MARC, MOMS, Prestera, Project Hope, Ohio Valley Physicians, Huntington Behavioral Health, the Methadone Clinic, and Valley Health all also bill insurance for part or all of the OUD and/or NAS treatment programs. *See* 6/7 Tr. (O'Connell) at 73:14–17, 74:12–19, 79:3–5, 82:13–15, 92:8–18, 122:20–23.

iii. Medicaid pays for the majority—86%—of NAS treatment for infants, and the majority of treatment for pregnant women with SUD in West Virginia. *See* 6/16 Tr. (Young) at 97:16–20, 97:23–98:1, 98:9–15.

iv. Dr. Werthammer testified that more than 75% of NAS charges at Cabell Huntington Hospital are paid for by Medicaid. *See* 5/21 Tr. (Werthammer), at 56:8–17.

e. Medicaid is a stable source of funding that is not grant-based, such that Medicaid-eligible individuals can remain on Medicaid unless their income increases sufficiently to make them no longer eligible. *See* 7/12 Tr. (Colston) at 99:1–12.

i. West Virginia has expanded coverage for substance use disorder treatment under the Medicaid Substance Use Disorder 1115 waiver. *See* 6/16 Tr. (Young) at 99:12–16; 7/12 (Colston) Tr. at 111:4–14.

ii. West Virginia applied for and received a 1115 waiver for substance use disorder treatment, with services beginning in 2018 and running through 2022, *see* 7/12 Tr. (Colston) at 113:10–19, and this can be extended for another five years. At the end of the waiver period, if the program is successful the state can also petition to make the services a permanent part of its Medicaid plan in perpetuity. *See id.* at 112:7–113:9.

iii. With the ACA expansion, the federal funding for Medicaid in West Virginia has increased by $84.9 million. *See* 7/12 Tr. (Colston) at 104:12–17.

f. The overwhelming majority of people in West Virginia have some form of health insurance.

i. 94% of people in West Virginia have health insurance. *See* 7/7 Tr. (Hughes) at 226:14–17; 7/12 Tr. (Colston) at 122:19–24.

ii. Approximately 26% to 33% of individuals in West Virginia are covered by Medicaid. *See* 7/12 Tr. (Colston) at 100:22–24; 7/7 Tr. (Hughes) at 226:23–25.

iii. Approximately 20% of individuals in West Virginia are covered by Medicare. *See* 7/12 Tr. (Colston) at 119:13–120:6.

246. Huntington and Cabell County do not pay for Medicaid or Medicare coverage. *See* 7/12 Tr. (Colston) at 118:11–15, 122:8–12.

247. The treatment costs in the Abatement Plan are based on the reimbursement rates provided for by West Virginia Medicaid. *See* 6/28 Tr. (Alexander) at 94:17–22, 95:10–11. Dr. Alexander testified that OUD treatment, including MAT, would be paid for by Medicaid for those people who are Medicaid-eligible. *See id.* at 127:9–12. MAT costs are also paid by private insurance. *See id.* at 127:15–17.

248. Huntington and Cabell County have been involved in administering or funding six programs that relate to the opioid crisis: LEAD, harm reduction, drug court/WEAR, the Turn Around Program, the Quick Response Team, and Compass. *See* 7/12 Tr. (Rufus) at 20:19–24, 21:2–7, 21:15–20, 22:4–23:5.

a. Those are the only programs funded or administered by the City or County that specifically address opioid issues. *See* 7/12 Tr. (Rufus) at 23:19–24.

b. In total, these six programs cost $2,070,708 as of 2019. *See* 7/12 Tr. (Rufus) at 26:6–11. Of that total cost, Huntington spent $136,520 annually: $5,162 in direct contributions and $131,358 through in-kind contributions. *See id.* at 24:21–23, 25:1–7. Approximately $1,934,188 of the total cost for these six programs was provided by grants and other third-party sources. *See id.* at 26:3–5.

c. The total cost of these programs (roughly $2 million annually) should remain steady even if grant funding is not available in the future. *See* 7/12 Tr. (Rufus) at 28:25–29:5.

249. Huntington did not experience increased costs due to the opioid epidemic. *See* 7/12 Tr. (Rufus) at 29:12–30:15; 31:15–21.

250. Cabell County had increased costs of approximately $2 million due to the opioid epidemic, because of increased payments to the regional jail system. *See* 7/12 Tr. (Rufus) at 31:22–33:5. The jail budget has now leveled off. *See id.* at 32:2–5. The only other increased cost for Cabell County attributable to the opioid epidemic was roughly $500,000 in the County Sherriff's budget. *See id.* at 32:18–33:1.

251. Plaintiffs' experts did not take into account whether Huntington or Cabell County have paid for or administered any opioid-related programs or services.

a. Dr. Alexander did not do any analysis of "costs or losses incurred by Cabell County or Huntington in the past" due to the opioid crisis or providing programs in response to the opioid crisis. 6/28 Tr. (Alexander) at 97:12–17.

b. Dr. Young did not evaluate whether any of the programs she considered are run or funded by Cabell County or Huntington. *See* 6/16 Tr. (Young) at 122:6–123:7.

c. Mr. Barrett did not evaluate whether Huntington or Cabell County provide or pay for treatment for opioid abuse and addiction, *see* 6/29 Tr. (Barrett) at 161:4–9, or whether they have ever paid for medical costs, *see id.* at 170:12–20. He also did not "consider how much the city or county currently spen[ds] on opioid-related programs" in developing the costs of the Abatement Plan. *Id.* at 120:1–3.

G. The Abatement Plan Includes Treatment and Other Programs to Serve Large Numbers of People Who May Become Addicted to Opioids in the Future.

252. The Abatement Plan includes an assumed number of people in Cabell/Huntington with OUD over the course of the 15 years covered by the Plan. *See* 6/28 Tr. (Alexander) at 145:19–24, 149:25–151:22. It assumes that a certain percentage of that OUD population receives medical treatment and other services over the 15 years covered by the Plan. *See id.* at 90:6–9.

253. Dr. Alexander conceded that the proposed Abatement Plan includes addiction treatment and other services for individuals in Cabell/Huntington who do not have OUD now, but may develop OUD in the future. *See* 6/28 Tr. (Alexander) at 150:10–13, 150:19–151:9.

a. Dr. Alexander testified that he cannot separate the number of people included in the Abatement Plan who develop OUD for the first time after 2021 (the starting year of the Plan), as compared the number of people with OUD as of 2021. *See* 6/28 Tr. (Alexander) at 153:22–154:12.

b. Dr. Alexander did not estimate how many people would develop OUD each year during the course of the Abatement Plan. *See* 6/28 Tr. (Alexander) at 153:5–10.

c. The OUD population included within the Abatement Plan would "include a child who is ten years old as of 2021 and has never used opioids [and] begins abusing heroin in 2027 as a teenager and develops OUD." 6/28 Tr. (Alexander) at 151:23–152:3.

d. The NAS population included within the Abatement Plan would include infants born to mothers who use opioids for the first time after 2021. *See* 6/28 Tr. (Alexander) at 154:24–155:6.

254. While Dr. Alexander did not identify the number of people treated under his Abatement Plan who will develop OUD for the first time after 2021, the evidence shows that a large majority of the treatment and other expenses included in the Abatement Plan are for individuals in Cabell/Huntington who develop OUD in the future.

a. The Abatement Plan assumes that 7,882 people have OUD in Cabell/Huntington as of 2021. *See* 6/28 Tr. (Alexander) at 156:17–21.

b. The Abatement Plan provides for treatment annually for approximately 3,000 people with OUD, *see* 6/28 Tr. (Alexander) at 155:22–157:3, and it assumes 365 days of treatment for any person with OUD, *see id.* at 159:15–22.

c. Dr. Waller testified that the one-year remission rate for OUD treatment is approximately 70%, and is as high as 84% in his clinic. *See* 5/4 Tr. (Waller) at 216:6–15.

d. If approximately 70% of people who receive treatment each year enter remission after one year, and the Abatement Plan assumes that approximately 3,000 people are receiving OUD treatment each year, after four years more than the entire assumed OUD population of 7,882 in Cabell/Huntington would have received OUD treatment (70% x 3,000 x 4 = 8,400). *See* 6/28 Tr. (Alexander) at 162:3–12.

e. Given that the Abatement Plan covers a 15-year period, and assumes treatment of approximately 3,000 people with OUD over each year of the Plan, more than 23,000 people are included within the Plan who develop OUD in the future assuming a 70% remisssion rate, as Dr. Waller testified (70% x 3,000 x 15 = 31,500). *See* 6/28 Tr. (Alexander) at 164:2–25.

255. Mr. Barrett testified that he cannot say what percentage of the total cost of the Abatement Plan is directed to treatment and other services for people who develop OUD in the future. *See* 6/29 Tr. (Barrett) at 197:2–7.

256. Plaintiffs presented no evidence of any future conduct by Defendants, nor any evidence that any future conduct by Defendants would cause individuals in Cabell/Huntington to develop OUD in the future.

H. The Abatement Plan Includes Treatment and Other Services for People Who Never Used a Prescription Opioid, or Whose Sole Exposure to Prescription Opioids Was Misuse.

257. The Abatement Plan provides for medical treatment and other services for people in Cabell/Huntington with OUD who have never taken a prescription opioid. *See* 6/28 Tr. (Alexander) at 119:20–120:1.

a. Dr. Alexander testified that "[i]f someone never touched a prescription opioid and in the future started using heroin, or fentanyl, or illegal fentanyl, or carfentanil and developed Opioid Use Disorder as a result of that use, treatment for their Opioid Use Disorder would be covered under [his] plan." 6/28 Tr. (Alexander) at 120:16–22.

b. The Abatement Plan would also provide medical treatment and other services to people in Cabell/Huntington with OUD who "started on illegal heroin, fentanyl, [or] carfentanil." 6/28 Tr. (Alexander) at 121:4–8.

c. The Abatement Plan provides for medical treatment and other services for intravenous drug users who have or develop HIV, endocarditis, or Hepatitis C. *See* 6/28 Tr. (Alexander) at 29:5–15, 120:7–15, 135:12–25. Dr. Alexander testified that there are individuals in Cabell/Huntington who have these medical issues who have never used a prescription opioid. *See id.* at 120:2–15.

d. The Abatement Plan provides for medical treatment and other services for infants born with neonatal abstinence syndrome (or "NAS"). *See* 6/28 Tr. (Alexander) at 66:1–9. Dr. Werthammer testified that NAS is not necessarily caused by exposure to prescription opioids and can arise from in utero exposure to non-opioids, *see*

5/21 Tr. (Werthammer) at 40: 6–18, 43:11–44:17, and from in utero exposure to illicit opioids such as heroin, *see id.* at 45:5–11.

258. The Abatement Plan provides for medical treatment and other services for individuals in Cabell/Huntington who have never had a medical prescription for opioids and whose only exposure to prescription opioids was through misuse. *See* 6/28 Tr. (Alexander) at 121:11–16.

259. Mr. Barrett did not determine how much of the total cost of the Abatement Plan is attributable to illicit opioids. *See* 6/29 Tr. (Barrett) at 120:14–16.

I. The Abatement Plan Is Based on an Unreliable Model.

1. The Starting OUD Population for the Abatement Model is Unreliable and Overestimates the Number of People with OUD.

260. A critical assumption for the Abatement Plan is the OUD population in Cabell/Huntington as of 2021 (the start of the 15-year period covered by the Plan), which Dr. Alexander assumed to be 7,882 people. *See* 6/28 Tr. (Alexander) at 156:17–21.

261. Dr. Alexander based his assumed OUD population for 2021 on an estimate of the Cabell/Huntington OUD population developed by Dr. Keyes. *See* 6/28 Tr. (Alexander) at 148:23–149:1, 176:21–25. Dr. Keyes estimated the Cabell/Huntington OUD population as of 2018. *See id.* at 146:3–6. Dr. Alexander's starting OUD population did not make any adjustments in the OUD population for the period between 2018 and 2020. *See* 7/12 Tr. (Rufus) at 47:25–48:11.

262. Dr. Alexander testified that if Dr. Keyes's OUD estimate is wrong, the OUD population assumed in the Abatement Plan is also wrong. *See* 6/28 Tr. (Alexander) at 149:15–23.

263. Dr. Keyes developed her estimate of the Cabell/Huntington OUD population based on a methodology that involved dividing the total number of overdose deaths from all drugs (the numerator) in Cabell/Huntington by an estimated mortality rate among people with OUD (the denominator). *See* 6/11 Tr. (Keyes) at 205:6–207:22.

264. Dr. Keyes testified that the accuracy of the overdose death number and the accuracy of the mortality rate is extremely important in reaching an accurate OUD estimate. *See* 6/14 Tr. (Keyes) at 134:4–9.

265. Dr. Keyes's estimated OUD population in Cabell/Huntington is unreliable and overestimates the number of people in Huntington and Cabell County with OUD, for two principal reasons. *See* 7/8 Tr. (Murphy) at 112:4–9.

266. First, Dr. Keyes's methodology overstates deaths, which causes her to overestimate the OUD population in Cabell/Huntington. *See* 7/8 Tr. (Murphy) at 111:19–112:3.

a. For purposes of estimating the OUD population in Huntington/Cabell, Dr. Keyes used the total number of overdose deaths from any drug, including from methamphetamine and cocaine. *See* 6/14 Tr. (Keyes) at 136:5–15.

b. Dr. Murphy testified that Dr. Keyes's methodology is flawed because Dr. Keyes's numerator—all overdose deaths in Cabell/Huntington, including people who do not have OUD—does not correspond to the population she is trying to estimate. *See* 7/8 Tr. (Murphy) at 108:18–24, 109:6–14.

267. Second, Dr. Keyes's methodology underestimates the mortality rate, which causes her to overestimate the OUD population in Cabell/Huntington. *See* 7/8 Tr. (Murphy) at 109:15–112:3.

a. Dr. Keyes made an adjustment to the estimated mortality rate to account for the increased lethality of fentanyl. *See* 6/14 Tr. (Keyes) at 143:25–144:4, 154:3–12, 158:15–23, 159:8–11. Dr. Keyes testified that if the fentanyl adjustment she applied is too low, it would result in overestimating the OUD population. *See id.* at 172:19–173:10.

b. In estimating the increased mortality rate associated with fentanyl, Dr. Keyes failed to take into account the fact that fentanyl mortality increased much more in the Eastern United States than the Western United States *See* 7/8 Tr. (Murphy) at 109:15–111:18, 113:22–114:11; *see supra* Findings ¶ 195. Taking into account the higher fentanyl mortality in the Eastern U.S. results in an OUD estimate of 5,496 people, without making any other adjustments to Dr. Keyes's methodology. *See* 7/8 Tr. (Murphy) at 114:12–17. This results in an OUD estimate that is approximately one-third smaller than Dr. Keyes's estimate, and is more accurate. *See id.* at 114:12–20, 115:13–17.

c. The correction in the fentanyl adjustment for the higher incidence of fentanyl mortality in the Eastern United States does not fix the other errors in Dr. Keyes's methodology and therefore does not result in a reliable OUD estimate. *See* 7/8 Tr. (Murphy) at 114:21–115:12.

268. Out of an estimated 8,252 people with OUD in Huntington/Cabell in 2018, Dr. Keyes opined that 5,800 (approximately 70%) of those cases are directly attributable to prescription opioids. *See* 6/14 Tr. (Keyes) at 173:24–174:4, 174:11–14, 174:18–24.

269. Out of an estimated 8,252 people with OUD in Huntington/Cabell in 2018, Dr. Keyes opined that 1,143 (approximately 14%) of those cases are not attributable to prescription opioids at all. *See* 6/14 Tr. (Keyes) at 175:21–176:7.

2. The Inputs Provided by Dr. Young are Unreliable.

270. The Abatement Plan is based on certain inputs from Dr. Young related to women with OUD who are pregnant or give birth to infants with NAS. *See* 6/16 Tr. (Young) at 104:23–105:7. Those inputs are unreliable because:

a. Dr. Young did not consider cost data from West Virginia when she developed her cost recommendations, even when comparable programs already existed in West Virginia. *See* 6/16 Tr. (Young) at 86:2–19, 90:5–8.

b. Dr. Young estimated five populations that are inputs into the Abatement Plan. *See* 6/16 Tr. (Young) at 104:23–105:7. None of those populations was based on data specific to Cabell/Huntington. *See id.* at 106:21–24, 107:5–13, 110:9–18, 111:10–17, 113:3–8, 113:16–18, 114:11–14. None of those populations was limited to women who developed OUD by abusing prescription opioids as opposed to other drugs. *See id.* at 118:2–6; *see also id.* at 31:5–11 (testifying "we really can't separate out opioids from other substances").

3. The Treatment Estimate of the Abatement Plan is Contradicted by the Resiliency Plan Developed by Local Experts.

271. Marshall Health coordinated drafting a long-term plan for addressing opioid abuse and addiction in the Cabell/Huntington community, entitled the "Resiliency Plan." *See* 5/28 Tr. (O'Connell) at 16:24–17:13, 18:22–19:14.

272. A "panel of experts and leaders in the community" was involved in drafting and reviewing the plan. 5/28 Tr. (O'Connell) at 19:21–23, 44:13–49:1. The group had extensive knowledge of addiction treatment and healthcare in Cabell/Huntington. *See id*. at 49:2–10. Many of these individuals, and others with expertise in healthcare and addiction, were involved in drafting or reviewing the plan. *See id.* at 49:22–51:10, 53:3–62:1. The Resiliency Plan was intended to be a "visionary plan" for dealing with the present and future effects of the opioid crisis. *See id.* at 82:2–13.

273. The Resiliency Plan was drafted assuming "unlimited resources." 6/7 Tr. (O'Connell) at 131:6–13.

274. The Resiliency Plan included cost projections for programs to address the opioid crisis, and included projected future costs for the treatment of opioid addiction and abuse. *See* 5/28 Tr. (O'Connell) at 64:10–65:12. These cost projections were for "four decades" of programs. *See id.* at 71:17–72:4.

275. A near-final draft of the Resiliency Plan projected $50 million for treatment costs, including all medical treatment for opioid abuse and addiction and for infants born with NAS. *See* 6/7 Tr. (O'Connell) at 91:9–21, 92:3–7, 132:22–133:1. Every draft of the Resiliency Plan that included funding allocations allotted between $23 million and $50 million for these long-term treatment costs. *See* Ex. DEF-WV-00929 at .00029; Ex. DEF-WV-01456 at .00001; Ex. DEF-WV-01457 at .00030; Ex. DEF-WV-01451 at .00030; Ex. DEF-WV-01447 at .00032.

276. The $50 million projection of treatment costs over four decades, and all other projected costs of the Resiliency Plan, were deleted from the Plan before it was published, in coordination with the lawyers representing Plaintiffs in this litigation. *See* 5/28 Tr. (O'Connell) at 108:24–112:20.

277. The Resiliency Plan, developed by local experts on the needs of the Cabell/Huntington community, projects treatment costs for opioid addiction and abuse and related medical services of $50 million over four decades. *See* 6/7 Tr. (O'Connell) at 91:9–21, 92:3–7, 132:22–133:1. This contradicts the Abatement Plan, which projects treatment and other medical costs of $2.1 billion over 15 years. *See supra* Findings ¶ 220.

a. Together, Dr. Alexander's proposed programs for treating opioid use disorder (for which Plaintiffs have requested $1,705,896,182), managing complications attributable to the epidemic (for which Plaintiffs have requested $301,682,032), and treatment and care for pregnant women, new mothers, and infants with opioid use disorder or neonatal abstinence disorder (for which Plaintiffs have requested $95,700,232) add up to $2,103,278,447. *See* 6/29 Tr. (Barrett) at 107:13–14, 107:14–16, 108:17–18.

278. Mr. Barrett testified that he did not consider the cost projections of the Resiliency Plan when developing the cost estimates of the Abatement Plan. *See* 6/29 Tr. (Barrett) at 167:10–14, 168:12–23.

4. The Cost Projections of the Abatement Plan Are Inflated and Unreliable.

279. The Abatement Plan includes a program for syringe exchange program to provide clean needles for IV drug users in Cabell/Huntington. *See* Tr. 6/28 (Alexander) at 135:12–25. The Abatement Plan includes projected costs for that syringe exchange program that are nearly 15 times the actual costs for such a program, and that reflect the unreliability of the Plan.

a. The Abatement Plan projects an annual cost of $872,614 to serve roughly 1,000 IV drug users, and a total cost of $12,619,008 over the 15-year period covered by the Plan. *See* 6/29 Tr. (Barrett) at 150:20–24, 151:2–7, 151:22-25.

b. By comparison, Dr. Feinberg testified that she ran a syringe services program that served roughly 1,400 to 1,500 people for $60,000 annually. *See* 6/17 Tr. (Feinberg) at 154:18–23, 183:10–20.

280. The Abatement Plan projects treatment costs that are unreliable and at odds with real-world experience, and which alone inflate the costs of the Plan by over $1 billion.

a. The Abatement Plan provides 365 days of treatment for the OUD population that receives regular outpatient treatment, and between 245–275 days of regular outpatient treatment for other treatment groups. *See* 6/28 Tr. (Alexander) at 165:16–21, 165:22–166:10, 169:25–170:7.

b. For 2018, based on federal government data, the actual median length of outpatient treatment was 71 days. *See* 6/7 Tr. (O'Connell) at 123:5–15, 124:17–125:2, 125:14–23, 126:9–14, 126:21–24; 6/28 Tr. (Alexander) at 166:24–167:19, 168:17–24.

c. If the Abatement Plan is adjusted to provide for 71 days of outpatient treatment, as reflected in actual experience, the total cost for OUD treatment in the Abatement Plan would be reduced by $1,061,849,848. *See* 7/12 Tr. (Rufus) at 46:22–47:1.

281. The Abatement Plan projects that over 15 years it will cost in excess of $1.7 billion to provide addiction treatment for approximately 3,000 people a year. *See* 6/29 Tr. (Barrett) at 158:3–13; 6/28 Tr. (Alexander) at 157:1–3. The actual experience in the Cabell/Huntington community contradicts this number. For example, PROACT provides addiction treatment services in Cabell/Huntington for at least 700 people a year at a cost of less than $1 million a year. *See* 6/7 Tr. (O'Connell) at 55:10–22, 56:21–23; Ex. DEF-WV-03542 (Marshall Health Addiction Services budget).

5. Dr. Alexander Deviated From His Own Methodology.

282. Dr. Alexander has submitted expert reports in three other opioid litigations that are comparable to the Abatement Plan in this case in projecting the programs and costs needed to address the opioid crisis in different communities. *See* 6/28 Tr. (Alexander) at 181:3–8, 181:9–14, 184:6–8, 187:21–23. In each of Dr. Alexander's other reports, he developed a "trend ratio" that projected the relevant OUD population based on a customized model developed by Dr. Alexander and his firm, and entitled "Apollo." *See id.* at 181:18–714, 182:8–22, 183:9–12, 185:11–17, 186:3–10, 188:7–10, 193:7–12.

283. Dr. Alexander deviated from that methodology when he developed his expert report for this litigation. He did not build an Apollo model for his report in Cabell/Huntington. *See* 6/28 Tr. (Alexander) at 192:25–193:2, 193:20–24.

a. Instead, Dr. Alexander's only cited support for the Abatement Plan trend ratio in this litigation was a paper by Homer et al. entitled a "Dynamic Model of the Opioid Epidemic with Implications for Policy." 6/28 Tr. (Alexander) at 190:8–25, 191:2–20, 191:25–192:4, 197:25–198:2.

b. Dr. Alexander further modified the findings of the Homer paper and provided only a single sentence of explanation in his expert report. *See* 6/28 Tr. (Alexander) at 195:25–196:18, 198:3–9.

c. Dr. Alexander did not test the Homer model. *See* 6/28 Tr. (Alexander) at 199:8–200:4. By comparison, Dr. Alexander tested and calibrated his Apollo model extensively in the other opioid litigations where he submitted it. *See* 6/28 Tr. (Alexander) at 183:19–25, 184:2–5.

d. Dr. Alexander also testified that whenever he develops a model like the Abatement Plan, he "consider[s] the background and training of authors" on which he relies as sources. *See* 6/28 Tr. (Alexander) at 201:10–18. However, Dr. Alexander did not know Homer, the author of the paper on whom he relied in this litigation, nor was he familiar with Homer's consulting company. *See* 6/28 Tr. (Alexander) at 200:21–201:20.

e. Dr. Alexander also testified that he "review[s]" and "consider[s]" the funding sources of papers he cites. *See* 6/28 Tr. (Alexander) at 202:8–15; 6/29 Tr. (Alexander) at 18:19–19:5. However, Dr. Alexander "wasn't aware" that the Homer paper was funded by two law firms that represent Huntington and Cabell County in this litigation, or that it was developed to be a damages model for the opioid litigation. *See* 6/28 Tr. (Alexander) at 201:21–202:12, 203:1–19, 203:24–205:6, 206:1–19.

J. Any Monetary Award Would Need To Be Converted To Present Value.

284. Mr. Barrett testified that all the monetary values in the Abatement Plan are in future dollars, not in present value. *See* 6/29 Tr. (Barrett) at 111:16–20.

285. Typically, forensic economists would calculate in present value on the assumption the payment would be a lump sum, *see* 6/29 Tr. (Barrett) at 112:3–8, and Mr. Barrett has never previously had a case where he did not reduce a final sum to present value, *see id.* at 195:6–10.

286. Mr. Barrett testified that if a lump sum is awarded, it should be reduced to present value, not future value. *See* 6/29 Tr. (Barrett) at 195:11–24.

287. The total cost for the Plan in present value, as calculated by Mr. Barrett, is $1,802,428,070. *See* 6/29 Tr. (Barrett) at 115:10–14.

CONCLUSIONS OF LAW

I. Public Nuisance

A. Inapplicability of Public Nuisance to Claims Based on Products

1. The Court concludes that the public nuisance doctrine is not applicable to Defendants' distribution of FDA-approved opioid medicines.

2. The Restatement (Third) of Torts states that public nuisance based on the distribution and sale of a product "has been rejected by most courts … because the common law of public nuisance is an inapt vehicle for addressing" that type of conduct. Restatement (Third) of Torts: Liability for Economic Harm § 8, cmt. g. The Restatement (Third) of Torts clarifies pre-existing principles of law set forth in the Restatement (Second) of Torts; it does not impose any new limitations on public nuisance causes of action. *Id*., cmt. a.

3. The West Virginia Supreme Court of Appeals has cited the Restatement of Torts favorably in articulating the scope of public nuisance under West Virginia law. *Duff v. Morgantown Energy Assocs.*, 187 W. Va. 712, 716 n.6, 421 S.E.2d 253, 257 n.6 (1992)

4. Influential public nuisance decisions from other jurisdictions have recognized that public nuisance law does not apply to claims based on the distribution and sale of a product.

   a. In *State v. Lead Industries. Ass'n*, 951 A.2d 428, 448 (R.I. 2008), the court stated that "a public right is more than an aggregate of private rights by a large number of injured people," and that "the manufacture and distribution of products rarely, if ever, causes a violation of a public right as that term has been understood in the law of public nuisance." The court further held that "[t]he law of public nuisance never before has been applied to products, however harmful." *Id.* at 456.

   b. In *Tioga Public School District v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993), the court concluded that if nuisance law were expanded to the distribution of products, it "would become a monster that would devour in one gulp the entire law of tort."

   c. In *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004), the court stated that it was "reluctant to recognize a public right so broad and undefined that the presence of any potentially dangerous instrumentality in the community could be deemed to threaten it."

   d. In *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2007), the court concluded that "[e]ven less support exists for the notion that the Legislature intended to permit these plaintiffs to supplant an ordinary product liability claim with a separate cause of action as to which there are apparently no bounds."

e. In *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 761 N.Y.S.2d 192, 196 (2003), the court concluded that "giving a green light to a common-law public nuisance cause of action today will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance."

f. In *Penelas v. Arms Technology, Inc.*, 1999 WL 1204353, at *6 (Fla. Cir. Ct. Dec. 13, 1999), the court concluded that "[p]ublic nuisance does not apply to the design, manufacture, and distribution of a lawful product."

5. There is no basis to apply public nuisance law to the distribution of an FDA-approved medicine to State-licensed and DEA-registered pharmacies, particularly in light of record evidence that:

a. Prescription opioids are FDA-approved medicines, and serve an important medical purpose in the treatment of pain, *see supra* Findings ¶¶ 20, 37;

b. Distribution of prescription opioids to pharmacies is essential in making those medicines available to patients who have a medical need for them, *see supra* Findings ¶ 7; and

c. It would be a significant public health concern if prescription opioids that have been prescribed by doctors for the treatment of pain were not distributed to pharmacies and therefore were not available to fill prescriptions for patients, *see supra* Findings ¶ 7.

6. As recognized by the Restatement (Third) of Torts, "[m]ass harms caused by dangerous products are better addressed through the law of products liability." Restatement (Third) of Torts: Liability for Economic Harm § 8, cmt. g.

7. The West Virginia Supreme Court has only applied public nuisance law in the context of conduct that interferes with public property or resources. In *Sharon Steel Corp. v. City of Fairmont*, 175 W. Va. 479, 483, 334 S.E.2d 616, 621 (1985), the Court stated that "[a] nuisance is anything which annoys or disturbs the free use of one's ***property***, or which renders its ordinary use or physical occupation uncomfortable …. A nuisance is anything which interferes with the rights of a citizen, either in person, ***property***, the enjoyment of his property, or his comfort …. A condition is a nuisance when it clearly appears that enjoyment of ***property*** is materially lessened, and physical comfort of persons in their homes is materially interfered with thereby …. When the prosecution of a business, of itself lawful, in a strictly residential neighborhood, impairs the enjoyment of homes in the neighborhood …."[10]

8. *Sharon Steel* included a near-exhaustive catalogue of West Virginia public nuisance cases from 1878 to 1982, stating:

[10] All emphases added unless otherwise noted.

> We have decided nuisance cases involving [1] land being used for rock concerts, [2] a school site near an airport, [3] dust created by coal trucks, [4] an automobile junk yard, [5] a used car lot, [5] a rail tramroad built on a public road, [6] a house of prostitution, [7] an automobile garage built out of inflammable materials, [8] fences, [9] coal smoke and soot emitted by a dye works plant, [10] a carpenter shop with a steam engine, [11] damage to property adjacent to a railroad track, [12] a merry-go-round, [13] explosives factory, [14] a house built partially on city property, [15] noise from a factory, and [16] an obstruction of a public road.

Id. Every case in that comprehensive listing concerns the misuse of, or interference with, public property or resources.

9. The West Virginia Supreme Court has never held that the distribution or sale of a *product* can constitute a public nuisance—especially not the distribution or sale of a lawful product that serves and important medical need and that is alleged to have caused injuries.

10. Plaintiffs assert a public nuisance claim based on the distribution and sale of a product—namely, prescription opioids—that caused personal injury.

11. "[I]n the absence of authority by the highest state court in West Virginia, [a federal court's] role in the exercise of our diversity jurisdiction is limited. A federal court acting under its diversity jurisdiction should respond conservatively when asked to discern governing principles of state law…. Therefore, in a diversity case, a federal court should not interpret state law in a manner that may appear desirable to the federal court, but has not been approved by the state whose law is at issue." *Mid-Vol Coal Sales, Inc. v. Balli Steel, PLC*, No. CV 1:11-0985, 2014 WL 12617727, at *3 (S.D.W. Va. Aug. 26, 2014) (Faber, J.) (citations and quotations omitted); *see also Rhodes v. E.I. DuPont de Nemours*, 636 F.3d 88, 96 (4th Cir. 2011) (holding that federal courts must "respond conservatively when asked to discern governing principles of state law").

12. There is no legal precedent that supports an *Erie* determination that the Supreme Court of Appeals of West Virginia would now expand public nuisance law beyond its traditional confines to encompass that alleged injury. Instead, there is every reason to believe the Supreme Court of Appeals of West Virginia would reject an expansion of public nuisance to cases (like this one) that involve the distribution and use of a product.

B. No Public Nuisance Claim for Defendants' Licensed Distribution in Response to Increased Good-Faith Prescribing

13. The Court concludes that Plaintiffs have failed to show that Defendants' conduct unreasonably interfered with a right common to the general public.

14. To establish a public nuisance, plaintiffs must prove, *inter alia*, "an unreasonable interference" by defendants "with a right common to the general public." *Duff v. Morgantown Energy Assocs.*, 187 W. Va. at 716 n.6, 421 S.E.2d at 257 n.6 (quoting Restatement (Second) of Torts § 821B); *see also* Memorandum Opinion and Order

(ECF No. 1294) at 2 (holding that plaintiffs must prove "the unreasonableness of the [defendant's] conduct").

15. Although conduct proscribed by statute or regulation ***may*** be a basis for concluding that an interference with a public right is "unreasonable," it is not "conclusive." *See* Restatement (Second) of Torts § 821B(2) (listing "whether the conduct is proscribed by a statute, ordinance or administrative regulation" as one of several factors that "may sustain a holding that an interference with a public right is unreasonable"); *see also id.*, cmt. e (the factors listed in subsection 2 "***are not conclusive tests*** controlling the determination of whether an interference with a public right is unreasonable").

16. When a plaintiff seeks to impose liability for public nuisance, the fact-finder must assess the gravity of and avoidability of the harm, as well as the primary purpose and utility of the defendants' conduct. *See Hendricks v. Stalnaker*, 181 W. Va. 31, 34, 380 S.E.2d 198, 201 (1989) ("In the area of public nuisance, we have made explicit that an examination of the 'reasonableness or unreasonableness of the use of property in relation to the particular locality' is a fair test to determine the existence of a public nuisance." (*quoting Sharon Steel Corp.*, 175 W. Va. at 480, 334 S.E.2d at 618)); Restatement (Second) of Torts § 828, cmt. a ("[I]n determining whether the gravity of the interference with the public right outweighs the utility of the actor's conduct, it is necessary to consider the social value that the law attaches to the primary purpose of the conduct, the suitability of the conduct to the character of the locality and the impracticability of preventing or avoiding the invasion.").

17. The Controlled Substances Act ("CSA") expressly recognizes that controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). Thus, the CSA's provisions reflect a balance between the need to protect public health from the dangers of controlled substances diverted into or produced for the illicit market with the equally important need to ensure that patients have access to pharmaceutical controlled substances for legitimate medical purposes.

18. The record evidence establishes that:

    a. Prescription opioids are FDA-approved medicines, and serve an important medical purpose in the treatment of pain, *see supra* Findings ¶¶ 20, 37;

    b. Distribution of prescription opioids to pharmacies is essential in making those medicines available to patients who have a medical need for them, *see supra* Findings ¶ 7;

    c. The West Virginia Board of Medicine and other influential healthcare organizations specifically approved and encouraged the use of prescription opioids to treat pain, *see supra* Findings ¶¶ 23–24, 26–27;

    d. DEA continually increased the aggregate production quotas for prescription opioids based on its determination of an increased legitimate medical need for those

medicines and to make sure those medicines were available to patients when doctors recognized a need to prescribe them, *see supra* Findings ¶¶ 71–74;

e. Pursuant to the change in the standard of care, doctors increased their prescribing of opioids for a broader range of conditions, most notably for the long-term treatment of chronic pain, *see supra* Findings ¶ 31–32;

f. The overwhelming majority of doctors—more than 99%—were acting in good faith when they prescribed opioid medicines for their patients, *see supra* Findings ¶ 45;

g. Defendants have no ability (or responsibility) to second-guess the good faith decisions of doctors to prescribe opioids to their patients, *see supra* Findings ¶ 9;

h. The increase in good-faith prescribing by doctors increased the volume of opioids shipped by Defendants, ordered by pharmacies, and subsequently available in the community, *see supra* Findings ¶¶ 41–45;

i. Defendants only shipped prescription opioids to licensed pharmacies in response to prescriptions, *see supra* Findings ¶ 52;

j. Serious public health concerns would be presented if distributors did not provide pharmacies with the pain medicines that have been prescribed by doctors because this would deprive patients of pain treatment that doctors have concluded is medically warranted, *see supra* Findings ¶ 7.

19. Given the fact that doctors' good-faith prescribing decisions determined the volume of prescription opioids ordered by pharmacies, and that Defendants have no ability to evaluate or second-guess those decisions, Defendants' conduct in shipping prescription opioid pills to licensed pharmacies so that patients could access the medicines they were prescribed cannot be deemed a public nuisance under West Virginia law. *See Pope v. Edward M. Rude Carrier Corp.*, 138 W. Va. 218, 226, 75 S.E.2d 584, 589 (1953) (conduct "which the public convenience imperatively demands[] cannot be a public nuisance") (citing 39 Am. Jur., Nuisances, Section 8).

20. Put another way, under the Restatement's formulation of a public nuisance, the distribution of medicine to support the medical needs of patients, as determined by doctors exercising their medical judgment in good faith, cannot be deemed an "unreasonable interference with a right common to the public," *Duff*, 187 W. Va. at 716 n.6, 421 S.E.2d at 257 n.6 (quoting Restatement (Second) of Torts § 821B).

21. Moreover, proof concerning the volume of prescription opioids distributed by Defendants, standing alone, does not satisfy Plaintiffs' burden of proving that ***Defendants' allegedly unreasonable conduct*** caused a public nuisance in Cabell/Huntington. As it relates to the overall volume of prescription opioids, and increases in that volume over time, the record evidence establishes that:

a. Cabell/Huntington is a hub for state-of-the-art health care in the region, and patients travel from a broad geographic area to obtain treatment at hospitals and subsequently fill prescriptions in Cabell/Huntington, *see supra* Findings ¶ 64–65;

b. The volume of prescription opioids dispensed by pharmacies in Cabell/Huntington reflects the volume of prescriptions written by doctors, *see supra* Findings ¶ 44;

c. Beginning in the 1980s, there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain, *see supra* Findings ¶ 22;

d. Beginning in the 1990s, the standard of care changed to recognize a broader range of appropriate uses for prescription opioids nationwide, including for the long-term treatment of chronic non-cancer pain, *see supra* Findings ¶ 23;

e. The West Virginia Board of Medicine and other influential healthcare organizations specifically approved and encouraged the use of prescription opioids to treat pain, *see supra* Findings ¶¶ 24, 26–27;

f. DEA continually increased the aggregate production quotas for prescription opioids based on its determination of an increased legitimate medical need for those medicines, *see supra* Findings ¶¶ 71–74; and

g. Pursuant to the change in the standard of care, doctors increased their prescribing of opioids for a broader range of conditions, most notably for the long-term treatment of chronic pain, *see supra* Findings ¶¶ 31–32;

h. The increase in good-faith prescribing by doctors pursuant to the then-prevailing standard of care determined the volume of opioids ordered by pharmacies and available in the community, *see supra* Findings ¶ 44;

i. Due to the characteristics of West Virginia's population, the change in the standard of care led West Virginia doctors to prescribe an even greater number of opioid pills than doctors in other states, *see supra* Findings ¶ 32; and

j. Defendants' conduct did not determine the volume of prescription opioids ordered by pharmacies and available in the community, *see supra* Findings ¶¶ 9, 30, 44, 51, 75.

C. Public Right

22. In addition to Plaintiffs' failure to prove an unreasonable interference by Defendants, the Court concludes that their public nuisance claim also fails because Plaintiffs did not prove that Defendants interfered with a public right.

23. For conduct to constitute a public nuisance, it must interfere with a right that is shared equally by the public, like access to air, water, or public rights-of-way—namely, a ***public right***. *Hark v. Mountain Fork Lumber Co.*, 127 W. Va. 586, 595–96, 34 S.E.2d

348, 354 (1945); Restatement (Second) of Torts § 821B(1) (a public nuisance is "an unreasonable interference with a right common to the general public").

24. The Restatement defines a public right both by what it is and what it is not. For purposes of a public nuisance claim, a public right (i) is a right common to all members of the public and (ii) is not like the individual or "private" right that everyone has not to be defrauded or negligently injured. *See* Restatement (Second) of Torts § 821B(1), cmt. g.

25. The distribution of FDA-approved prescription opioids to state-licensed, DEA-registered pharmacies that ordered the medications to fill prescriptions written by state-licensed doctors does not interfere with a public right.

26. The right asserted by Cabell/Huntington is based on the injuries suffered by those who abused and became addicted to opioids, or those in the community who were adversely affected by opioid abuse and addiction. No such injuries occurred unless individuals used opioids. Such injuries, and the downstream effects on the community related to those private rights, concern the private rights that everyone has not to be negligently defrauded and negligently injured, and all flow from individual conduct involving the ingestion of opioids. *See supra* Findings ¶ 112(b) (opioid abuse and addiction cannot occur without ingestion of opioids). Likewise, downstream effects on the community from opioid abuse and addiction are the result of individual acts of opioid use. These are entirely unlike public rights to clean air and clean water or access to public property and rights-of-way, and instead involve the adverse effects on individuals who were exposed to and adversely affected by opioids.

27. Plaintiffs argue that the opioid crisis in Cabell/Huntington constitutes a public nuisance because a large number of individuals suffered from addiction and/or opioid use disorder. But the fact that Defendants' conduct is alleged to have interfered with many people's ***individual, private rights*** does not change the character of the underlying right itself. The Restatement is explicit that the private right not to be "defrauded or negligently injured" is a right "everyone has" and many can be affected by the fraud or negligent conduct. *See* Restatement (Second) of Torts § 821B(1), cmt. g; *see also Lead Indus.*, 951 A.2d at 436, 453 ("[A] public right is more than an aggregate of private rights by a large number of injured people.").

28. The fact that opioid abuse and addiction of Cabell/Huntington residents affected other persons in the community—family, friends, business colleagues, first responders—also does not transform the interference with private rights into interference with a public right. It is true of many, if not most, personal injury and wrongful death cases that there are family members and others who suffer economic loss and, along with first responders, emotional distress. But West Virginia law strictly circumscribes bystander recovery. *See, e.g.*, *State ex rel. Maxxim Shared Servs., LLC v. McGraw*, 242 W. Va. 346, 352, 835 S.E.2d 590, 596 (2019) ("bystander recovery is limited to a narrow group of 'closely related' individuals"). And the West Virginia Supreme Court has never held that the existence of bystanders who suffered emotional distress or economic loss converted a personal injury claim into a public nuisance.

29. If Defendants shipped too many pills and individuals became injured or addicted as a result, then, at most, Defendants have interfered with those individuals' private rights not to be injured—but no public right has been implicated. The *City of Chicago* and *Lead Industries* cases make this very point:

a. In *City of Chicago*, the plaintiffs alleged the exact same type of widespread public harm as Plaintiffs here allege—"a higher level of crime, death, and injuries to Chicago citizens, a higher level of fear, discomfort, and inconvenience to the residents of Chicago, and increased costs to the [city] to investigate and prosecute crimes caused by the illegal possession and use of the firearms brought into Chicago." 821 N.E.2d at 1115–16. But the Illinois Supreme Court rejected the notion that the breadth of the impact of gun violence on the community as a whole was sufficient to establish that gun manufacturers or distributors had interfered with any public right in over-supplying or mis-marketing handguns, concluding:

> "[W]e do not intend to minimize the very real problem of violent crime and the difficult tasks facing law enforcement and other public officials. Nor do we intend to dismiss the concerns of citizens who live in areas where gun crimes are particularly frequent. Rather, we are reluctant to state that there is a public right to be free from the threat that some individuals may use an otherwise legal product (be it a gun, liquor, a car, a cell phone, or some other instrumentality) in a manner that may create a risk of harm to another." *Id.* at 1116.

b. The Rhode Island Supreme Court held the same with respect to lead paint. The widespread poisoning of children from lead paint in houses no doubt had far-reaching impact on more than just the injured children and their families, but that did not change the essential character of the rights at issue from private to public. *See Lead Indus.*, 951 A.2d at 436. As the court explained, it was "undisputed that lead poisoning constitutes ***a public health crisis*** that has plagued and continues to plague this country, particularly its children," but "[t]he state's allegation that defendants have interfered with the 'health, safety, peace, comfort or convenience of the residents of the [s]tate' standing alone does not constitute an allegation of interference with a public right." *Id.* at 453. Rather, "[t]he term public right is reserved more appropriately for those indivisible resources shared by the public at large, such as air, water, or public rights of way." *Id*.

30. Like West Virginia, both Illinois and Rhode Island follow the Restatement with respect to their common law of public nuisance. *See City of Chicago*, 821 N.E.2d at 1111 ("The Restatement definitions of public and private nuisance are consistent with Illinois law."); *Lead Indus.*, 951 A.2d at 446 ("our definition [of public nuisance] largely is consistent with … the Restatement (Second) of Torts").

D. Fault Standard

31. Under West Virginia law, a defendant cannot be held liable for public nuisance unless the interference with the public right was intentional or was otherwise actionable under

the principles concerning liability for negligent or reckless conduct or for abnormally dangerous activities. Thus, Plaintiffs must prove that Defendants engaged in conduct that (1) was intentional, (2) was negligent, or (3) amounts to an abnormally dangerous or ultrahazardous activity. Restatement (Second) of Torts § 821B, cmt. e; *see also Hendricks*, 181 W. Va. at 33–34, 380 S.E.2d at 200–01.

32. Furthermore, Defendants may not be held liable on a public nuisance theory merely for the lawful operation of their pharmaceutical distribution business, but only for *wrongful* conduct. *See, e.g.*, *Sharon Steel Corp.*, 175 W. Va. at 483, 334 S.E.2d at 620; *see also* Memorandum Opinion and Order (ECF No. 1248) at 14 (stating that "the relevant conduct" in this lawsuit is "not the lawful business of pharmaceutical drug distribution").

33. Plaintiffs did not allege and did not prove that this case involves an abnormally dangerous activity. The Supreme Court of Appeals of West Virginia has held that coal mining is not an abnormally dangerous activity because the risks of harm can be greatly reduced by the exercise of due care. *In re Flood Litig.*, 216 W. Va. 534, 545, 607 S.E.2d 863, 874 (2004). So, too, the distribution of FDA-approved prescription medications by DEA-regulated and state-licensed wholesale distributors to DEA-regulated and state-licensed pharmacies can be done safely—and thus it does not constitute an abnormally dangerous activity under West Virginia law.

34. Plaintiffs also did not establish any intentional wrongdoing by Defendants. An interference with a public right is intentional if the defendant "acts for the purpose of causing [the consequence of his act]" or "knows that [the consequence] is resulting or is substantially certain to result from his conduct." Restatement (Second) of Torts § 825; *see also id.* § 8A ("The word 'intent' is used throughout the Restatement of this Subject to denote that the actor desires to cause consequences of his act, or that he believes that the consequences are substantially certain to result from it."); *Hendricks*, 181 W. Va. at 35 ("An interference is intentional when the actor knows or should know that the conduct is causing a substantial and unreasonable interference."); ECF No. 1446.31.

    a. Plaintiffs did not present any evidence to show that any Defendant "intended to bring about" the "opioid crisis" in Cabell/Huntington or intended to harm at all. Nor did Plaintiffs present any evidence that Defendants intended to cause an "oversupply" of pills.

    b. Instead, the evidence in the record is to the contrary. Defendants shipped only the amount of pills ordered to fill the prescriptions written by doctors, no more and no less. Defendants delivered (i) FDA-approved medications (ii) only to state-licensed pharmacies who ordered them (iii) to fill prescriptions issued by state-licensed physicians.

35. Plaintiffs cannot prove negligence as a matter of law because the statutory and regulatory schemes upon which Plaintiffs rely do not give rise to any enforceable legal duties and thus cannot support a public nuisance cause of action.

a. Under West Virginia law, there is no negligence as a matter of law unless the defendant owes a duty that runs to the plaintiff. *See, e.g.*, *Yourtee v. Hubbard*, 196 W. Va. 683, 699, 474 S.E.2d 613, 619 (1996) ("[A] common law negligence theory cannot proceed unless there is a duty owed by the alleged culpable person ***to the injured person***."). The CSA and West Virginia Controlled Substances Act ("WVCSA") do not create any duties running from Defendants *to Plaintiffs*. *See infra* Conclusions of Law ¶¶ 102–115.

b. And neither the CSA nor the WVCSA were enacted to protect city or county governments from opioid-related harm. *See, e.g.*, Opinion and Order, *In Re: National Prescription Opiate Litig.*, N.D. Ohio, No. 1:18-op-45749 (June 13, 2019), ECF No. 67 at 24 (Polster, J.) (holding that government entities are "not the intended beneficiaries of the CSA," and stating that the CSA was not enacted "to protect [governments] … from spending more on addiction-related public services when the rates of addiction increase").

36. Plaintiffs have stated that the underpinning of their public nuisance claim is alleged violations of the federal CSA and WVCSA. But, as a matter of law, an alleged violation of the CSA or WVCSA cannot provide the basis for a public nuisance claim.

a. As a matter of law, Plaintiffs cannot base their public nuisance claim on alleged violations of the CSA because the statutory and regulatory schemes may not be privately enforced—neither directly nor indirectly.

b. Only Congress can authorize a private lawsuit for violations of a federal statute. *See Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) ("Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress."); *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 118 (2011) ("Recognition of any private right of action for violating a federal statute … must ultimately rest on congressional intent to provide a private remedy.") (internal quotation marks, citation, and alteration omitted).

c. Congress did not include an express private right of action in the CSA permitting private enforcement of the statute and its implementing regulations. *See* 21 U.S.C. §§ 803-904. Congress instead granted the United States Attorney General exclusive authority to enforce the CSA. The Attorney General has delegated that enforcement authority exclusively to DEA. *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2016).

d. Nor is there an implied private right of action to enforce the CSA. And nothing in the text or structure of the CSA suggests that Congress intended to confer a private remedy on the states or their counties and cities. *See Smith*, 164 F. Supp. 3d at 1290; *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 793 n.16 (S.D.W. Va. 2001) (finding no such "legislative intent"). "[F]ederal courts [including in the opioid litigation] have uniformly held that the CSA does not create a private right of action." *Smith*, 164 F. Supp. 3d at 1290; *see also, e.g.*, *West Virginia v.*

McKesson Corp., Case No. 2:17-03555, ECF No. 21 at 14–15 (S.D.W. Va. Feb. 15, 2018).

e. Nor may Plaintiffs enforce the CSA indirectly through a common law cause of action. *See, e.g.*, *Astra USA, Inc.*, 563 U.S. at 118 (holding that a private party could not indirectly enforce a provision of the Public Health Services Act, which contains no private right of action and may be enforced only by the Secretary of HHS, through a state law breach of contract claim); *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994) (permitting a plaintiff to enforce statutory or regulatory duties through common law negligence claims "would, in effect, be permitting a private cause of action" under the statute).

f. The same is true when it comes to the WVCSA. Like the CSA on which it is modeled, the WVCSA does not include a private right of action.

g. Nor does the WVCSA create an implied right of action: (1) Plaintiffs are not "member[s] of the class for whose benefit the statute was enacted"; (2) the legislature did not "intend[]" to create a private right of action; (3) Plaintiffs' cause of action is not "consistent with the underlying purposes of the legislative scheme"; and (4) Plaintiffs' cause of action would intrude into an area delegated exclusively to the State. *Hurley v. Allied Chem. Corp.*, 164 W. Va. 268, 278, 262 S.E.2d 757, 763 (1980).

h. Plaintiffs argue that they do not seek to enforce the CSA because their claim is one for public nuisance. But the nature of Plaintiffs' claim is irrelevant—what matters is that Plaintiffs' public nuisance claim ***depends*** on proving a violation of the CSA and WVCSA. As *Astra USA, Inc.* makes clear, a federal statute with no private right of action cannot be the linchpin for a state-law claim. *See, e.g.*, AmerisourceBergen Drug Corporation's Reply Mem. in Support of Mot. for Judgment Under Rule 52(c) Based on Pls.' Failure to Prove Culpable Conduct (ECF No. 1489) at 30–35.

E. No Actionable Conduct

37. Plaintiffs admit that, in order to prevail on their public nuisance claims, they must prove, at a minimum, actionable (*i.e.*, unreasonable) conduct on the part of Defendants that was a substantial factor in bringing about the opioid crisis in Cabell/Huntington. *See* Mem. of Law in Opp. to Defs.' Mot. for Summary Judgment on Proximate Causation Grounds (ECF No. 1080) at 12. The Court finds and concludes that Plaintiffs have failed to demonstrate that.

38. The evidence demonstrates that Defendants (1) only shipped opioids to State-licensed and DEA-registered pharmacies, and (2) never shipped for any purpose other than to fill a prescription written by a doctor. *See supra* Findings ¶¶ 6, 52.

39. There is no evidence that diversion of prescription opioids in Cabell/Huntington occurred while under Defendants' control. *See supra* Findings ¶ 106. There is also no evidence of any diversion by Defendants' pharmacy customers in Cabell/Huntington.

See id. ¶¶ 53, 108. To the contrary, the only record evidence of pharmacy-level diversion in Cabell/Huntington is A-Plus Care Pharmacy in Barboursville, which no Defendant serviced. *See id.* ¶¶ 109–110. The lack of any evidence of pharmacy-level diversion on the part of Defendants' pharmacy customers is fatal to Plaintiffs' claims.

40. The record evidence reflects that the principal form of diversion in Cabell/Huntington was "medicine cabinet diversion," *i.e.* the diversion of unused prescription opioid pills dispensed by a pharmacy pursuant to a legitimate prescription that are subsequently sold, given away or stolen. *See supra* Findings ¶ 113. Plaintiffs' witnesses admitted that it is not the role of wholesale distributors to prevent this type of diversion. *See id.* ¶ 114. The Court therefore concludes that Defendants had no duty to prevent medicine cabinet diversion.

41. Plaintiffs have argued that the total volume of prescription opioids that Defendants shipped into Cabell/Huntington is itself proof of wrongdoing, but the Court rejects that argument. The evidence reflects that the quantity of prescription opioids that Defendants distributed was determined entirely by the prescribing decisions of doctors, and that shipment volume increased due to an increase in good-faith prescribing by doctors. *See supra* Findings ¶¶ 41–45. There is no evidence that Defendants played any role in doctors' prescribing decisions or otherwise determining the volume of prescription opioids available in Cabell/Huntington. *See id.* ¶¶ 9, 30, 44, 51, 75; *see also infra* Additional Witness-Specific Findings ¶¶ 113–122.

42. The Court likewise rejects Plaintiffs' argument that evidence regarding so-called "outlier" pharmacies and doctors is evidence of wrongdoing by Defendants.

    a. Identification of pharmacies that ordered more opioids than national and state averages proves nothing other than the mathematical certainty that, whenever a large number of measurements are averaged, a significant portion of the individual data points will be above average. No witness testified that above-average ordering by a particular pharmacy is itself evidence of wrongdoing by that pharmacy—let alone by the distributor that supplied it. There is no evidence of any improper pharmacy order or illegitimate prescribing facilitated by Defendants' shipments in Cabell/Huntington. *See supra* Findings ¶¶ 53, 108; *see also infra* Additional Witness-Specific Findings ¶¶ 143–146.

    b. Plaintiffs also identify a number of so-called "outlier" pharmacies outside Cabell/Huntington—some as far as 165 miles away—that Defendants serviced. But there is no evidence of any nexus between Defendants' shipments to those pharmacies and any diversion or harm in Cabell/Huntington. Accordingly, the Court concludes as a matter of law that liability for those shipments may not be imposed on Defendants in this action.

    c. Identification of individual doctors who prescribed more opioids than national and state averages likewise is not evidence of wrongdoing by Defendants, for the same reasons. In addition, the record evidence reflects—and the Court concludes—that

Defendants have neither the ability nor any duty to police of second-guess the good-faith prescribing decisions of doctors. *See supra* Findings ¶ 9.

43. Plaintiffs criticize Defendants for failing to block shipment of "suspicious orders" prior to 2008. But the Court finds and concludes that:

a. A "suspicious order," as that term is used in 21 C.F.R. § 1301.74, is different from an order that is likely to be diverted, and represents a much broader category of orders;

b. At all relevant times, all Defendants blocked orders that they determined were likely to be diverted, *see supra* Findings ¶ 141;

c. Neither the federal CSA nor its implementing regulations—to this day—set forth any obligation to block shipment of suspicious orders, *see infra* Conclusions of Law ¶¶ 102–115;

d. Prior to 2007, DEA understood and accepted that wholesale distributors would ship any "suspicious orders" that they identified and reported to DEA, *see supra* Findings ¶ 139, 142;

e. In 2007, DEA for the first time announced revised, sub-regulatory guidance indicting that wholesale distributors should not ship "suspicious orders," *see infra* Conclusions ¶ 143–146;

f. By 2008, each Defendant had put in place a new SOM system that ***blocked all suspicious orders*** the Defendant identified, *see supra* Findings ¶ 148.

g. No witness testified that the thresholds used by Defendants for purposes of flagging potentially suspicious orders when they put their new systems in place in or around 2008 were set too high.

44. Plaintiffs asserted that Defendants shipped a large quantity of "suspicious orders" to their pharmacy customers in Cabell/Huntington. The only witness who supported that assertion, however, was Mr. Rafalski, and the Court finds and concludes that Mr. Rafalski's flagging and other opinions were not supported by a reliable methodology and were not credible. *See supra* Findings ¶¶ 153–165; *see also infra* Additional Witness-Specific Findings ¶¶ 65–76.

45. The Court further finds that Mr. Rafalski's *ipse dixit* opinion that his "flagged" orders were more likely than not diverted was not supported by a reliable methodology and was not credible. *See supra* Findings ¶¶ 153–165; *see also infra* Additional Witness-Specific Findings ¶¶ 65–76.

46. In short, the Court finds and concludes that the testimony of Mr. Rafalski, even if admitted, establishes neither that (1) Defendants shipped "suspicious orders" to customers in Cabell/Huntington or (2) those orders were dispensed by those pharmacy

customers for any purpose other than to fill a legitimate prescription written in good faith by a doctor.

F. No Evidence of Current Public Nuisance

47. Plaintiffs assert that the only relief they are seeking is forward-looking abatement of the alleged public nuisance. *See infra* Conclusions of Law ¶¶ 123.

48. In this forward-looking case, Plaintiffs therefore are required to establish, at a minimum, that Defendants' ***current*** conduct constitutes a ***current*** public nuisance in Cabell/Huntington.

49. Plaintiffs have not presented any evidence of ***current*** conduct by Defendants that could support a finding of a current public nuisance in Cabell/Huntington, or that Defendants' past conduct constitutes a current public nuisance in Cabell/Huntington. The entirety of Plaintiffs' evidence related to Defendants' conduct is stale and not current. In particular, the record evidence establishes that:

a. Opioid prescribing in Cabell/Huntington has decreased by more than 50% since 2013 and is now within the bounds of medically accepted practice, *see supra* Findings ¶¶ 68–69;

b. Shipments of oxycodone and hydrocodone in Cabell/Huntington have decreased by roughly half from their peak, and are down to a level similar to what they were in 2005, *see supra* Findings ¶¶ 68–69;

c. Plaintiffs presented no evidence that current levels of prescription opioid shipments into Cabell/Huntington are excessive or causing harm;

d. Plaintiffs presented no evidence related to any of Defendants' conduct in Cabell/Huntington that is more recent than 2013, *see infra* ABDC-Specific Facts ¶¶ 135–146; Cardinal Health-Specific Facts ¶¶ 31–40; McKesson-Specific Findings ¶¶ 71–76;

e. Defendants always blocked and did not ship orders that were identified as likely to be diverted, *see supra* Findings ¶ 141;

f. By no later than 2008, each Defendant had in place a suspicious order monitoring program that blocked and did not ship orders determined to be "suspicious," *see supra* Findings ¶ 148;

g. There is no evidence of any wrongdoing with respect to Defendants' suspicious order monitoring programs post-2013, *see infra* ABDC-Specific Facts ¶¶ 135–146; Cardinal Health-Specific Facts ¶¶ 31–40; McKesson-Specific Findings ¶¶ 71–76;

h. There is no evidence that Defendants ever shipped any orders other than in response to an order placed by a State-licensed and DEA-registered pharmacy, *see supra* Findings ¶¶ 6, 44; and

i. There is no evidence that any of the prescription opioids shipped by Defendants in Cabell/Huntington ever left a pharmacy shelf absent a legitimate prescription written by a State-licensed and DEA-registered doctor, *see supra* Findings ¶¶ 40–45, 48–49, 51–53.

50. Evidence concerning an allegedly "excessive" volume of opioids shipped by Defendants prior to 2013, standing alone, is not relevant and thus insufficient to prove that Defendants' ***current*** conduct constitutes a public nuisance in Cabell/Huntington.

51. Evidence concerning alleged shortcomings in Defendants' suspicious order monitoring programs prior to 2013, standing alone, is not relevant and thus insufficient to prove that Defendants' ***current*** conduct constitutes a public nuisance in Cabell/Huntington.

G. Standing

52. Under West Virginia law, counties and municipalities may only seek to abate a public nuisance that has been (i) "recognized as such per se" or (ii) designated as such "by lawful statute or ordinance." Syl. 1, *Parker v. City of Fairmont*, 72 W. Va. 688, 79 S.E. 660 (1913).

53. This standing rule stems from the fact that municipalities and county commissions lack general, inherent powers and may exercise only those powers expressly conferred by the West Virginia Constitution and the Legislature. *See* Syl. Pt. 2, *State ex rel. Charleston v. Hutchinson*, 154 W. Va. 585, 176 S.E.2d 691 (1970).

54. A per se nuisance is "an act, occupation, or structure which is a nuisance at all times and under any circumstances." *Duff*, 187 W. Va. at 716 n.8, 421 S.E.2d at 257 n.8.

55. "[A] lawful business . . . authorized to be conducted by the government cannot constitute a nuisance *per se*." *Burch v. Nedpower Mount Storm, LLC*, 220 W. Va. 443, 456-57, 647 S.E.2d 879, 892-93 (2007).

56. Defendants' lawful distribution of FDA-approved prescription opioid medications through a supply chain authorized and regulated by the federal and state governments cannot be considered "a nuisance at all times and under any circumstances." *Duff*, 187 W. Va. at 716 n.8, 421 S.E.2d at 257 n.8. Thus, Plaintiffs cannot prove a nuisance per se.

57. Plaintiffs have not enacted an ordinance of general applicability that would permit Plaintiffs to seek abatement of the alleged public nuisance in this case. *See Donohoe v. Fredlock*, 72 W.Va. 712, 79 S.E. 736, 737 (1913).

58. Cabell County's 2017 resolution and Huntington's 2020 resolution do not have the force of law, do not define the offending conduct, and, at most, can apply only to conduct post-dating their enactment and thus cannot confer standing for claims predating their enactment. Plaintiffs' resolutions are insufficient to confer standing.

59. Plaintiffs lack standing to bring public nuisance claims against Defendants.

60. Testimony of the corporate designee for Cabell County reflects that that the County does not believe it holds the authority to engage in abatement programs directed to drug abuse and drug addiction. *See, e.g.*, B. Thompson (Cabell Cty. 30(b)(6) designee) 7/23/20 Dep. Designations at 35:5–23, 40:3–41:1, 45:14–46:15, 47:14–48:1, 110:4–8, 133:13–134:17.

II. Causation

61. The Court concludes that Plaintiffs have failed to prove the required elements of causation-in-fact and proximate causation.

62. Plaintiffs cannot recover against Defendants by proving only that they were injured as a result of the opioid crisis.

63. Plaintiffs also must prove causation-in-fact and proximate causation. *See, e.g.*, Pls.' Mem. of Law in Opp. to Defs.' Mot. for Summary Judgment on Proximate Causation Grounds (ECF No. 1080) at 5 (Plaintiffs conceding that they must prove that Defendants "were ***a*** proximate cause" of their alleged injuries) (citing *Everly v. Columbia Gas of W. Virginia, Inc.*, 171 W. Va. 534, 536 (1982)) (emphasis in Plaintiffs' brief); *City of Charleston v. Joint Commission*, 473 F. Supp. 3d 596, 627 (S.D. W. Va. 2020) ("West Virginia defines proximate cause 'as that cause which, in actual sequence, unbroken by any independent cause, produced the event, without which such event would not have occurred.'" (quoting *Webb v. Sessler*, 135 W.Va. 341, 63 S.E.2d 65, 68 (1950)); Syl. Pt. 1, *Mays v. Chang*, 213 W. Va. 220, 579 S.E.2d 561.

A. No Causation-In-Fact

64. For the following three reasons, the Court finds and concludes that Plaintiffs failed to prove that Defendants' alleged wrongdoing was a cause-in-fact of their claimed injury.

65. First, Plaintiffs presented no evidence that, had any Defendant performed more or better due diligence regarding pharmacy orders, it would have had reason to block any more orders than it did, much less any significant number of orders. Indeed, the Court finds that the evidence is to the contrary: the increasing volume of orders for prescription opioids received by Defendants reflected increased good-faith prescribing by Cabell/Huntington doctors in conformity with the prevailing standard of care. *See supra* Findings ¶¶ 41–45.

66. Second, Plaintiffs presented no evidence that, had any Defendant blocked more pharmacy orders, any pharmacy customer would not have been able to fill the order with another distributor. Indeed, the Court finds that the evidence is to the contrary: pharmacies would have had no difficulty in directing their business to other wholesale distributors, of which there were many.

67. Third, Plaintiffs presented no evidence that, had any Defendant reported more pharmacy orders as suspicious, the DEA would have taken effective enforcement action against the doctors prescribing opioids or the pharmacies dispensing them. Indeed, the Court finds that the evidence is to the contrary: the DEA endorsed the

prevailing standard of care, which supported the long-term use of opioids to treat chronic pain, and took the position during the relevant period that 99% of doctors were prescribing opioids in conformity with the standard of care. *See supra* Findings ¶ 45.

B. No Proximate Causation

68. The Court likewise finds that Plaintiffs failed to establish proximate causation.

69. The Supreme Court of Appeals of West Virginia has acknowledged that actionable conduct "which renders a defendant liable for damages must be a proximate, ***not a remote***, cause of injury." *Metro v. Smith*, 146 W. Va. 983, 990, 124 S.E.2d 460, 464 (1962); *see also* Mem. of Law in Support of Defs.' Mot. for Judgment on Partial Findings Regarding Proximate Causation (ECF No. 1440-1) at 12–14.

70. The remoteness prong of proximate causation requires that Plaintiffs must prove a "***direct relation*** between the injury asserted and the injurious conduct alleged." *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992); *see also Employer Teamsters-Local Nos. 175/505 Health & Welfare Tr. Fund v. Bristol Myers Squibb Co*., 969 F. Supp. 2d 463, 473–75 (S.D. W. Va. 2013) (concluding that the "directness" standard from *Holmes* provided "guiding principles in assessing proximate causation" and applying the *Holmes* standard to West Virginia state law claims); *City of Charleston*, 473 F. Supp. 3d at 628 (discussing *Holmes* and concluding that "courts have applied the principles of remoteness to state law tort claims insofar as proximate cause requires 'carefully drawing a line so as to distinguish the direct consequences in a close causal chain from more attenuated effects influenced by too many intervening causes'").

71. This remoteness standard under West Virginia law is clearly reflected in decisions from this District holding that proximate causation could not be established where the alleged harm was unduly remote from the challenged conduct.

    a. In *Employer Teamsters*, Judge Chambers found no proximate causation because "[b]etween Defendants' alleged misleading marketing and Plaintiffs' prescription reimbursements lies a vast array of intervening events, including the independent medical judgment of doctors." 969 F. Supp. 2d at 475

    b. In *City of Charleston*, Judge Copenhaver found no proximate causation because "no injury would occur" unless a doctor made a medical decision to prescribe opioids and because the claims relied on "various criminal actions of third parties." 473 F. Supp. 3d at 631.

72. Plaintiffs' core theory of harm is based on the diversion of prescription opioids.

    a. Plaintiffs' theory, however, is not that any prescription opioids entered Cabell/Huntington after being diverted while in Defendants' custody or under their control. Nor does the record evidence support such a theory.

    b. Nor does the record evidence support any assertion that Defendants' pharmacy customers were engaging in diversion. Rather, the only record evidence of

pharmacy-level diversion relates to a pharmacy that was not serviced by any of the Defendants. *See supra* Findings ¶ 109–110.

c. Instead, Plaintiffs' theory is that prescription opioids were diverted to illicit channels and misused ***after*** the medicines were delivered by Defendants to state-licensed and DEA-registered pharmacies and dispensed by those pharmacies pursuant to prescriptions written by doctors. *See supra* Findings ¶¶ 112–113.

73. At least four independent actions—including two exercises of professional judgment and two crimes—had to occur before Cabell/Huntington residents could be harmed by the type of "medicine cabinet diversion" that lies at the core of Plaintiffs' theory.

a. The opioid medicines that Defendants distributed would have sat on a pharmacy shelf, reaching no one and causing no harm, but for the independent actions of two different medical professionals: (1) the doctor who prescribed the medications and (2) the pharmacist who dispensed them. *See supra* Findings ¶¶ 40–45, 48–49, 51–53.

i. By law, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner"—not wholesale distributors. 21 C.F.R. § 1306.04(a).

ii. In addition, "a corresponding responsibility rests with the pharmacist who fills the prescription" to ensure that a prescription is proper prior to dispensing the prescription to a patient. *Id.*

iii. Defendants have no comparable "corresponding responsibility" under the governing regulations.

b. Moreover, two additional acts, both illegal, must have occurred: (1) the opioid must have been diverted to illegal use; and (2) someone must have illegally possessed and used the diverted opioid. *See supra* Findings ¶ 115.

c. Only after all these actions occurred were Plaintiffs even in a position to be harmed by diverted prescription opioids, and then only if the diversion led to addiction, overdose or criminal activity.

74. Under these circumstances, Plaintiffs' claims fail the remoteness test of West Virginia law.

a. Among other infirmities, Plaintiffs' theory of harm depends on independent prescribing decisions by doctors, which makes the claim unduly remote. *See City of Charleston*, 473 F. Supp. 3d at 631 ("The independent medical judgment of the prescribing physicians further breaks the chain of causation" because "no injury would occur unless the physician proceeded to unnecessarily prescribe opioid treatments or if patients obtained the drugs through some other illegal means"); *Employer Teamsters*, 969 F. Supp. 2d at 475 (finding claims unduly remote because of "intervening events, including the 'independent medical judgment' of doctors").

The record evidence clearly demonstrates that the increased volume of prescription opioids in the Cabell/Huntington community was driven by doctors' good faith prescribing decisions, based on the then-prevailing standard of care. *See supra* Findings ¶¶ 41–45. Thus, even if the volume of prescription opioids was excessive when viewed in hindsight, that volume was the result of doctors' prescribing decisions and Defendants were not the proximate cause of that volume or the harms flowing from that volume.

b. Plaintiffs' theory of harm also depends on at least two intervening criminal acts (illegal diversion and illegal misuse), a further reason that the claims are unduly remote. *See City of Charleston*, 473 F. Supp. 3d at 631 ("Plaintiffs' claims rely on various criminal actions of third parties" and therefore "defendants' actions are too attenuated an influenced by too many intervening causes, including the criminal actions of third parties, to stand as the proximate cause of plaintiffs' injuries."). Diversion from medicine cabinets, after the pills are dispensed by a pharmacy, involves multiple criminal acts. *See supra* Findings ¶ 115. Further, the record is replete with evidence of criminal drug trafficking in Cabell/Huntington, which increased the supply of both legal and illegal opioids in the community and therefore contributed significantly to Plaintiffs' alleged opioid-related harms. *See supra* Findings ¶¶ 169–178.

c. Plaintiffs' own witnesses, including their putative diversion expert (Mr. Rafalski) and the former head of the DEA's Office of Diversion Control (Mr. Rannazzisi) admitted that Defendants have neither the ability nor the responsibility to prevent this type of "medicine cabinet" diversion that occurs long after the prescription opioids shipped by Defendants leave their possession and control. *See supra* Findings ¶ 114.

75. Injuries from the use of prescription opioids can occur even if the medicines are used as intended and are not diverted or misused. Defendants, however, are not the legal cause of any such injuries.

a. The responsibility for ensuring that prescription opioids are used only for legitimate medical purposes rests with prescribers and pharmacists—not wholesale distributors. *See* 21 C.F.R. § 1306.04(a).

b. Defendants, as wholesale distributors, have neither the duty nor the ability to prevent patients from receiving medicines prescribed in good faith by their doctors. *See supra* Findings ¶ 9.

c. Plaintiffs failed to demonstrate proximate causation as to any harm caused when Cabell/Huntington residents took a lawful prescription as prescribed. If a patient fills a lawful prescription, uses the medicine as intended, and becomes addicted, Defendants may not as a matter of law be held responsible for that addiction or any downstream costs associated with the addiction. Instead, such injuries are said to be "*damnum absque injuria*, for which no recovery could be had." *See Guyan*

Motors, Inc. v. Williams, 133 W. Va. 630, 635, 57 S.E.2d 529, 532 (1950) (no recovery where party "could not prove a duty but could prove damage").

76. Plaintiffs argue that they have satisfied their burden of proving proximate causation by presenting evidence—principally from Dr. Keyes—that there is a "causal association between the supply of prescription opioids in Cabell/Huntington and the increase in opioid-related harms." *See, e.g.*, Pls.' Mem. of Law in Opp. to Defs.' Mots. for Judgment on Partial Findings on Causation (ECF No. 1469) at 13. But that evidence—even if true—does not establish that Defendants were a proximate cause of Plaintiffs' alleged harm.

a. As an initial matter, Dr. Keyes made clear that when she refers to "supply," she is referring to opioid pills that are out in the community and being used or abused by individuals—*e.g.*, pills that have ***already left*** the closed system of distribution and are being consumed by end-users. *See* 6/14 Tr. (Keyes) at 10:20–25.

b. Moreover, the record evidence—including from Dr. Keyes—demonstrates that the increase in the volume of opioids available in Cabell/Huntington was not caused by Defendants, but rather by the increase in the number of prescriptions written by doctors in good faith based on the then-prevailing standard of care. *See supra* Findings ¶¶ 44–45; *see also* 6/14 Tr. (Keyes) at 82:19–22 ("the opioid crisis ***would not have occurred*** if prescribing opioids had not become standard practice in managing acute and chronic pain").

c. Accordingly, because Defendants did not cause the increase in opioid availability, any correlation or even causal connection between opioid availability and harm would not establish proximate causation ***as to Defendants***.

77. Plaintiffs also predicate their claims in substantial part on injuries flowing from the use of non-prescription opioids, such as heroin and illicit fentanyl.

a. The record evidence demonstrates that there has been a significant decline in opioid prescribing in Cabell/Huntington since 2013, and a corresponding decline in prescription opioid distribution. *See supra* Findings ¶¶ 68. In particular:

i. Opioid prescribing in Cabell/Huntington has decreased by more than 50% since 2013, *see supra* Findings ¶ 68(b)–(c);

ii. Opioid prescribing in Cabell/Huntington is now within the bounds of medically accepted practice, *see supra* Findings ¶ 69;

iii. Shipments of oxycodone and hydrocodone in Cabell/Huntington have decreased by roughly half from their peak, and are down to a level similar to what they were in 2005, *see supra* Findings ¶ 68(a);

iv. Plaintiffs have failed to present sufficient evidence that the current levels of good-faith opioid prescribing or corresponding distribution are excessive.

b. The record evidence further demonstrates that there is an extensive amount of illegal drug trafficking activity in Cabell/Huntington, and that in recent years, the use and abuse of ***illegal drugs*** like heroin and illicit fentanyl has been the major driver of opioid-related injury in Cabell/Huntington. *See supra* Findings ¶ 176.

78. For three reasons, Defendants cannot be held liable for harms caused by illegal drugs such as heroin and illicit fentanyl.

79. *First*, just as with prescription opioids, Plaintiffs' claims with respect to illegal opioids fail for lack of cause-in-fact. *See supra* Conclusions of Law ¶¶ 64–67. Criminal actors—not Defendants—are responsible for trafficking illegal drugs into Cabell/Huntington, and there is no evidence that but for Defendants' alleged conduct, harms from illegal drugs would not have occurred. *See supra* Findings ¶¶ 166–178, 196.

80. *Second*, Plaintiffs cannot establish proximate causation for harms caused by illegal drug abuse, addiction and overdoses. These injuries are even more attenuated and indirect than those associated with the diversion and abuse of prescription opioids, and so likewise fail West Virginia law's remoteness test for proximate causation.

a. Defendants do not distribute illegal drugs such as heroin and illicit fentanyl; drug traffickers do that. *See supra* Findings ¶¶ 182–183.

b. Moreover, even accepting Plaintiffs' theory as true, each of the following would be necessary before Defendants' conduct could cause any harms flowing from the use of illegal, non-prescription opioids:

i. a Cabell/Huntington resident becomes addicted to prescription opioids wrongfully distributed by a Defendant;

ii. the resident transitions from prescription opioids to illegal opioids;

iii. a drug trafficker delivers illegal opioids into the community;

iv. a drug dealer sells the illegal opioids to the resident; and

v. the resident illicitly consumes the illegal opioids.

See, e.g., *supra* Findings ¶ 183, 214–215.

c. Any connection between Defendants' conduct and injuries flowing from the use of illegal opioids is too remote as a matter of law. *See, e.g.*, *City of Charleston*, 473 F. Supp. 3d at 631 (remoteness test not satisfied where "[p]laintiffs' claims rely on various criminal actions of third parties, such as illegal drug trafficking"); *see also Harbaugh v. Coffinbarger*, 209 W.Va. 57, 64 543 S.E.2d 338, 345 (2000) (decedent's decision to play Russian roulette was "[a]n intervening cause ... making it and it only, the proximate cause of the injury" even though defendant had supplied the loaded gun); *Yourtee*, 196 W. Va. at 690, 474 S.E.2d at 620

("Generally, a willful, malicious, or criminal act breaks the chain of causation."); *Bertovich v. Advanced Brands & Importing, Co.*, 2006 WL 2382273, at *11 (N.D. W.Va. Aug. 17, 2006) (holding that "illegal acts of third parties breaks the necessary chain of causation"); *Ashworth v. Albers Med., Inc.*, 410 F. Supp. 2d 471, 478–82 (S.D. W.Va. 2005) (drug manufacturer not liable for injuries caused by alleged criminal acts of third parties introducing counterfeit versions of the manufacturer's drug into the stream of commerce).

81. *Third*, even putting aside their inability to establish proximate causation, Plaintiffs' assertions of a causal "gateway" between prescription opioids and later illegal drug abuse is wholly unsupported by the evidence. Plaintiffs rest their entire gateway theory on evidence that many heroin users previously abused prescription opioids, but Plaintiffs did not present sufficient evidence that prior abuse of prescription opioids ***causes*** later illegal drug abuse.

a. The evidence reflects that the overwhelming majority of heroin users who previously abused prescription opioids ***also abused many other illegal drugs***. *See supra* Findings ¶¶ 206–207.

b. The evidence reflects that heroin users who previously misused prescription opioids have a broader substance abuse problem, and that the sequence of abuse of prescription opioids before heroin abuse does not establish that one caused the other. *See supra* Findings ¶¶ 206–207, 211.

III. Derivative Injury

82. In West Virginia, common law rules remain in effect "until altered or repealed by the Legislature." W. Va. Const. art. VIII, § 13.

83. "The usual common law rule is that a [third-party payor] has no direct cause of action in tort against one who injures the provider's beneficiary, imposing increased costs upon the [payor]." *United Food & Com. Workers Unions, Emps. Health & Welfare Fund v. Philip Morris, Inc.*, 223 F.3d 1271, 1274 (11th Cir. 2000) (citing *Anthony v. Slaid*, 52 Mass. 290, 290–91 (1846)). Thus, "[f]or more than 100 years state and federal courts have adhered to the principle (under both state and federal law) that the victim of a tort is the proper plaintiff, and that … third-party providers of assistance and medical care to the victim may recover only to the extent their contracts subrogate them to the victim's rights." *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Tr. Fund v. Philip Morris Inc.*, 196 F.3d 818, 822 (7th Cir. 1999).

84. This common law rule bars Plaintiffs' claim. Plaintiffs seek to recover the costs of providing addiction treatment and other medical care and assistance to their residents. But the proper plaintiff for any such claim would be the injured residents themselves. Because Plaintiffs do not assert valid subrogation rights, their claim—which is entirely derivative of their residents' claims—fails as a matter of law.

IV. Free Public Services Doctrine

85. Under the free public services doctrine, "absent authorizing legislation, the cost of public services … is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the service." *District of Columbia v. Air Fla., Inc.*, 750 F.2d 1077, 1080 (D.C. Cir. 1984).

86. The Supreme Court of Appeals of West Virginia has endorsed the principles underlying the doctrine, disallowing claims to recover from inmates "the costs of room and board in the county jail" as a "charge upon the county or state" that cannot be recovered "in the absence of statutory authority." *State v. St. Clair*, 177 W. Va. 629, 630–31, 355 S.E.2d 418, 419–20 (1987).

87. The free public services doctrine applies to claims that purport to seek equitable abatement. *See, e.g.*, *Walker County v. Tri-State Crematory*, 284 Ga. App. 324, 328, 643 S.E.2d 324, 328 (2007) (rejecting proposed exception for claims seeking abatement because "many expenditures … could be re-characterized by skillful litigants as expenses incurred in abating a public nuisance").

88. Plaintiffs seek to recover costs of providing public services such as addiction treatment, employment programs and family support to their residents. Because no legislation authorizes cities or counties in West Virginia to recover for such expenditures from alleged tortfeasors, Plaintiffs' claim is barred by the free public services doctrine.

V. Statute of Limitations

89. Under West Virginia law, the statute of limitations for a nuisance claim is one year. W. Va. Code § 55-2-12(c).

90. The one-year statute of limitations applies even where a plaintiff seeks the equitable relief of abatement. *Taylor v. Culloden Public Serv. Dist.*, 214 W. Va. 639, 647, 591 S.E.2d 197, 205 (2003). Thus, Plaintiffs may not assert claims based on conduct that occurred more than one year before they filed suit. *Henry v. Ohio River R. Co.*, 40 W. Va. 234, 21 S.E. 863, 866 (1895).

91. Plaintiffs knew or should have known of their claims as of June 2012, and admit that their "claims first arose or accrued prior to May 25, 2015." Pls.' Mem. of Law in Supp. of Mot. to Strike Defs.' Notices of Non-Party Fault (ECF No. 225) at 10.

92. Plaintiff Huntington filed its lawsuit on January 19, 2017. Plaintiff Cabell County filed its lawsuit on March 9, 2017.

93. Because Plaintiffs did not sue until 2017, they cannot assert claims based on pre-2016 conduct.

94. Application of the continuing-tort doctrine does not save Plaintiffs' claims based on conduct that occurred more than one year before they filed their lawsuits.

a. Tortious conduct is deemed "continuing" only "where events, which for all practical purposes are [i] identical, [ii] occur repeatedly, [iii] at short intervals, [iv] in a consistent, connected, rhythmic manner." *DeRocchis v. Matlack, Inc.*, 194 W. Va. 417, 423 n.4, 460 S.E.2d 663, 669 n.4 (1995).

b. Moreover, the doctrine applies as a general rule to continuing conduct, not continuing (*i.e.*, permanent or lingering) injury. *See State ex. rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 200 W. Va. 221, 245 n.29, 488 S.E.2d 901, 925 n.29 (1997) (noting that under the general West Virginia rule a "continuing tort sufficient to toll the statute of limitations is occasioned by *continual unlawful acts*, not by continual ill effects from an original violation" (emphasis in original)); *see also Roberts v. W. Virginia Am. Water Co.*, 221 W. Va. 373, 655 S.E.2d 199 (2007); *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751 (S.D.W. Va. 2009), and *Graham v. Beverage*, 211 W. Va. 466, 566 S.E.2d 603 (2002).

c. Defendants' allegedly wrongful conduct is not the kind that is "continuing" in nature. Each shipment of medicines by Defendants is a discrete and separate event, made in response to discrete and separate orders placed by pharmacies, whose characteristics and ordering histories themselves changed over time. Moreover, the decisions to make (or to report to regulators) such shipments were made by Distributors using policies and procedures that changed over time.

d. Even if the continuing-tort doctrine applies, it serves only to preserve claims for conduct that occurred within the limitations period that, absent a continuing tort, would have expired. *See Taylor*, 214 W. Va. at 647 n.21, 591 S.E.2d at 205 n.21 (applying the continuing tort doctrine, but explaining that "the damages that [the plaintiffs] can recover … are ***limited to the two-year period in time prior to filing of their* [*nuisance*] *cause of action***"). If the continuing tort doctrine applies, and Plaintiffs had proven their nuisance claim, they could, at most, seek relief for alleged wrongful conduct that occurred within the one-year statutory period before filing suit—*i.e.*, since January 2016 (Huntington) or March 2016 (Cabell County). The continuing-tort doctrine does not "toll" claims that accrued outside the statutory period. *Henry*, 40 W. Va. 234, 21 S.E. 863; *Patrick v. Sharon Steel Corp.*, 549 F. Supp. 1259, 1266 (N.D.W. Va. 1982).

95. The West Virginia Supreme Court held that, in a case "brought in order to remediate a business site containing hazardous waste," a public nuisance claim does not accrue until the hazardous wastes are no longer present in the environment (in amounts exceeding regulatory limits). *See Kermit Lumber*, 200 W. Va. at 245, 488 S.E.3d at 925. That rule, which was expressly limited to the hazardous waste context, has no applicability here. *Id.* at 245 n.29, 925 n.29 ("We make clear that in the case before us, we are only concerned with a public nuisance involving hazardous waste which is found in the soil and leaching into a river. A different public nuisance action may warrant a different analysis.").

96. But even assuming, as Plaintiffs contend, that the accrual rule announced in *Kermit Lumber* applies to this case, Plaintiffs' claims are time-barred.

a. In *Kermit Lumber*, the court held that the statute of limitations had not yet begun to run because the alleged nuisance—*i.e.*, the presence of arsenic "on the Kermit Lumber business site in amounts above the regulatory limits"—had not yet been remediated. *See* 200 W. Va. at 245, 488 S.E.2d at 925.

b. By analogy here, the nuisance alleged in this case—which consists of allegedly shipping too many prescription opioid pills into Cabell/Huntington—would remain until the prescription opioid pill levels shipped into Cabell/Huntington by Defendants were no longer "excessive" and not in violation of Defendants' purported regulatory obligations.

c. The statute of limitations would therefore begin to run when the presence of "excessive" opioid pills in Cabell/Huntington allegedly attributable to Defendants' conduct—*i.e.*, opioid pills distributed by Defendants in alleged violation of their purported regulatory obligations—was remediated.

d. The evidence reflects a 50% decline in opioid prescribing and shipments, and that current levels of prescribing in Cabell/Huntington are within accepted practice. *See supra* Findings ¶¶ 68–69.

97. Plaintiffs filed suit on March 9, 2017 (Cabell County) and January 19, 2017 (Huntington). Accordingly, the alleged public nuisance must have continued through at least March 9, 2016 to fit within the one-year limitations period.

98. Plaintiffs have presented no credible evidence that any Defendant made any "improper" shipments of opioid medicines into Cabell/Huntington at any time after 2013. *See infra* ABDC-Specific Facts ¶¶ 135–146; Cardinal Health-Specific Facts ¶¶ 31–40; McKesson-Specific Findings ¶¶ 71–76. In fact, the exact opposite is true: Plaintiffs stated that Defendants' current suspicious order monitoring programs—which have been in place since at least 2012—are irrelevant to the alleged "flood" of opioids at issue in this lawsuit. *See, e.g.*, 5/14 Tr. at 10 ("And, finally, on the relevance standpoint, eliciting testimony about current customers or current [suspicious order monitoring] programs, we fail to see how it has anything to do with the flood of pills that were sold into West Virginia, into this community, giving rise to the opioid epidemic.").

99. The record evidence, moreover, demonstrates that Defendants' distribution of prescription opioids into Cabell/Huntington began rapidly decreasing in 2014. *See supra* Findings ¶¶ 68; *see also* ECF No. 1441.1 at 3.

100. Accordingly, Plaintiffs' claims are time-barred in their entirety.

101. The statute of limitations does not bar government entities from seeking to enjoin an ongoing nuisance. Plaintiffs, however, are not seeking to enjoin Defendants' conduct and have not presented sufficient evidence of an ongoing nuisance.

VI. There Is Not a "No Ship" Duty Under the CSA

102. Plaintiffs predicate their claims in part on the assertion that Defendants violated various "duties" arising out of the CSA and its implementing regulations. That federal regulatory scheme, however, does not proscribe any conduct and does not create any independent legal "duties" enforceable by Plaintiffs in this litigation. In particular, it does not set forth any "duty" not to ship "suspicious orders."

103. The CSA provides that (1) every person who manufactures, distributes, or dispenses controlled substances must apply for registration with DEA and periodically renew that registration and (2) registered wholesale distributors may ship controlled substances only to dispensers who have an active registration. *See* 21 U.S.C. §§ 822(a)–(b); 21 C.F.R. § 1301.74(a).

104. DEA "shall register an applicant" unless it determines "that the issuance of such registration is inconsistent with the public interest." *See* 21 U.S.C. § 823(b).

105. "In determining the public interest" for purposes of registration, revocation, or suspension, the statute instructs DEA to consider certain factors, including the applicant's "maintenance of effective control[s] against diversion." *See* 21 U.S.C. § 823(b)(1). The CSA and its implementing regulations thus concern the registration process for wholesale distributors.

106. In assessing the factors set forth in the CSA and its implementing regulations to determine whether a registration should be issued, suspended, or revoked, DEA must determine whether the registered entity has "substantially complied" with the regulatory provisions. Put differently, substantial compliance with the relevant requirements may be deemed sufficient by DEA. *See* 21 C.F.R. § 1301.71(b).

107. The factors set forth in the CSA and its implementing regulations largely address the physical handling and security of controlled substances, including specifications for storage areas, cabinets, vaults, cages, alarms, compounding areas, and the like. *See, e.g.*, 21 C.F.R. § 1301.72.

108. As part of the "effective controls" provisions of the CSA, registrants are required to (i) "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and (ii) "inform" DEA "of suspicious orders when discovered." *See* 21 C.F.R. § 1301.74(b). This is the only provision in the CSA regulations that mentions suspicious orders.

109. This provision does not proscribe any conduct and does not create independent legal "duties." Rather, it merely sets forth one component of DEA's broad assessment of the registrant's "overall security system" for purposes of determining whether the registrant is in "[s]ubstantial compliance" with the effective controls provisions. *See* 21 C.F.R. § 1301.71(b). That assessment is used, in turn, to determine only whether registration is "[]consistent with the public interest," *see* 21 U.S.C. § 823(b), ***not*** whether the registrant has acted "unlawfully" or should be subject to civil or criminal

penalties. The assessment does not create independent legal duties that are enforceable by Plaintiffs in this litigation.

110. Federal regulations require a distributor to check that its shipments are to DEA-registered pharmacies and prescribers prior to shipment. *See* 21 C.F.R. § 1301.74(a). This license check is the only customer due diligence required of distributors under federal law.

111. Neither the CSA nor its implementing regulations impose any requirement on Defendants not to ship "suspicious orders."

112. It was not until 2020 that DEA, for the first time, proposed new regulations that would require distributors to conduct "due diligence" and not to ship orders meeting the regulatory definition of "suspicious orders" unless and until additional due diligence showed that the order was not likely to be diverted. *See* 85 Fed. Reg. 69,282, RIN 1117–AB47 (Nov. 2, 2020). Those new proposed regulations have not yet been approved or taken effect. If these requirements already existed in the regulations, it would not make sense for DEA to commence notice-and-comment rulemaking to implement these requirements.

113. The record reflects that, in late 2007, DEA provided informal, sub-regulatory guidance that suspicious orders should not be shipped. *See supra* Findings ¶¶ 143–144. To the extent that sub-regulatory guidance could establish a legal "duty" on behalf of distributors not to ship suspicious orders (and it cannot for the reasons stated above), there is no evidence that DEA asked Defendants not to ship suspicious orders until late 2007. *See supra* Findings ¶¶ 143–144; *see also U.S. v. $463,497.72 in U.S. Currency*, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) (identifying September 11, 2007 as the date on which DEA "told distributors" about its "***new interpretation*** of the suspicious order regulation); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 222 (D.C. Cir. 2017) (identifying the July 2007 *Southwood* administrative decision as when DEA "***first articulated***" its revised guidance).

114. The relevant portions of the WVCSA and related regulations are nearly identical to the equivalent provisions of the CSA and related regulations. The WVCSA, like the CSA, does not impose any "duties" on wholesale distributors to report or block shipment of suspicious orders.

115. There is no evidence that any Defendant shipped any suspicious orders after 2008, shortly after DEA provided this informal sub-regulatory guidance that suspicious orders should not be shipped. *See supra* Findings ¶ 148.

VII. Federal Preemption

116. To the extent Plaintiffs' claims are premised on violations of purported "duties" arising under the CSA, those claims are preempted by federal law.

117. State law is preempted when it stands as an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399–400 (2012).

118. In enacting the CSA, Congress sought to strike an important balance. The CSA is designed not only to prevent the misuse of controlled substances, but also to foster the beneficial use of those medications. *See Gonzalez v. Raich*, 545 U.S. 1, 24 (2005).

119. DEA is obligated not only to investigate diversion, but also to ensure that there is no interference with the dispensing of controlled substances to Americans in accordance with the sound medical judgment of their physicians.

120. Congress created a comprehensive enforcement scheme that vests DEA with authority to enforce the CSA—including the regulatory provisions relating to identifying and informing DEA about "suspicious orders." Congress, moreover, granted DEA discretion in exercising this enforcement authority because that federal agency has the expertise to balance the CSA's competing aims of "foster[ing] the beneficial use of those medications" and "prevent[ing] their misuse." *Gonzalez*, 545 U.S. at 24.

121. Plaintiffs' claims focus only on alleged harms from opioids and risks of diversion. Because Plaintiffs' claims disrupt the delicate regulatory balance Congress intended DEA to achieve in enforcing the CSA, they stand as an obstacle to the accomplishment of the purposes and objectives of Congress in enacting the CSA and of DEA in regulating under it.

122. Accordingly, Plaintiffs' claims are preempted by federal law.

VIII. Plaintiffs' Proposed "Abatement" Remedy

123. Plaintiffs seek "only the equitable remedy of abatement"; they "have waived all claims for damages, including punitive damages." *See* Mem. of Law in Support of Plaintiffs Motion to Strike Defendants Notices of Non-Party Fault (ECF No. 225) at 5; *see also* Mem. of Law in Support of Defs.' Mot. for Judgment on Partial Findings Regarding Abatement (ECF No. 1451) at 7–8 & n.15.

124. The Court finds that Plaintiffs are not entitled to any abatement relief in this case for the following reasons.

A. The Court, As a Matter of Federal Equity Jurisdiction, Lacks Power To Grant Plaintiffs' Requested Equitable Relief.

125. Federal common law defines the power of the federal court to award equitable relief. State law can neither enlarge nor limit that power.

a. A federal court exercising diversity jurisdiction applies the substantive law of the state under which the claims arise, but it "has long been the province of federal courts sitting in equity to apply a body of federal common law irrespective of state

law." *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 839 (9th Cir. 2020) (citing *Russell v. Southard*, 53 U.S. 139, 147 (1851)).

b. State law can neither limit nor enlarge the equitable remedies available in federal court. Whatever the state law claim, a federal court exercising diversity jurisdiction can award equitable relief—whether an injunction, restitution, disgorgement, or abatement—only if a legal remedy is inadequate. *See Sonner*, 971 F.3d at 841; *SSMC, Inc. v. N.V. Steffen*, 102 F.3d 704, 708 (4th Cir. 1996).

126. A federal court can only award equitable relief if there is no adequate legal remedy. *See Guaranty Trust Co. of New York v. York*, 326 U.S. 99, 105 (1945) (holding that "[e]quitable relief in a federal court is of course subject to restrictions," including that "a plain, adequate, and complete remedy at law must be wanting"); *see also* Mem. of Law in Support of Cardinal Health's Mot. for Judgment (ECF No. 1446) at 40–43 (collecting authority).

127. The test of adequacy is not whether the plaintiff would have recovered damages had he pursued a legal remedy. Rather, it is whether the plaintiff has potential legal claims. *See, e.g., McKesson HBOC, Inc. v. New York State Common Ret. Fund, Inc.*, 339 F.3d 1087, 1093 (9th Cir. 2003).

128. Damages are an adequate and available remedy, as Plaintiffs alleged in suing for public nuisance, negligence, and RICO violations. *See* Third Amend. Compl. ¶¶ 1475, 1548. But Plaintiffs waived their claim for damages. *See supra* Conclusions of Law ¶ 123.

129. A federal court cannot make a purely monetary award as equitable relief. Any monetary award must be adjunct to traditional equitable relief.

a. In *Guaranty Trust Co. v. York*, as discussed above, the Supreme Court held that "[e]quitable relief in a federal court is of course subject to restrictions," the first of which is that "the suit must be within the traditional scope of equity as historically evolved in the English Court of Chancery." 326 U.S. at 105. "State law cannot define the remedies which a federal court must give simply because a federal court in diversity jurisdiction is available as an alternative tribunal to the State's courts." *Id.* at 106.

b. In *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), the Supreme Court addressed the traditional scope of equity. The Court explained that "a [monetary] recovery could not be obtained through an independent suit in equity if an adequate legal remedy were available." But a federal court has the power "to award complete relief" where "the equitable jurisdiction of the court has properly been invoked for injunctive purposes." *Id.*

c. In *Mertens v. Hewitt Associates*, 508 U.S. 248, 255 (1993), the Supreme Court again addressed the traditional scope of equitable relief. In affirming dismissal of the claim, the Court said:

> Petitioners maintain that the object of their suit is "appropriate *equitable* relief" under § 502(a)(3) (emphasis added). They do not, however, seek a remedy traditionally viewed as "equitable," such as an injunction or restitution. … Although they often dance around the word, what petitioners in fact seek is nothing other than compensatory damages—monetary relief for all losses their plan sustained as a result of the alleged breach of fiduciary duties.

130. Abatement is a traditional equitable remedy, but similar to *Mertens*, Plaintiffs do not seek abatement in its traditional sense. *See State v. AmerisourceBergen Drug Corp.*, Nos. 20-0694 & 20-0751 (June 11, 2021) (Hutchison, J., concurring) ("'Abatement' is an equitable form of relief and is simply the 'act of eliminating or nullifying' whatever is causing the public nuisance.") (quoting Garner, Black's Law Dictionary (11th ed. 2019)); *see* E.R. Hardy Ivamy, Mozley & Whiteley's Law Dictionary (11th ed. 1983) (defining "Abatement of nuisances" as "their removal"); Dictionary of Law (5th ed. 2007) (defining "abatement" as "the legal right to remove or stop a nuisance"); Merriam-Webster's Dictionary of Law (2011) (defining "abate" as "to put an end to or do away with (~ a nuisance)"); J. Law, Dictionary of Law (8th ed. 2015) (defining "abatement (of nuisances)" as the "termination, removal, or destruction of a nuisance"); S. Giftis, Law Dictionary (7th ed.) (defining "abatement of a nuisance" as "the removal, termination or destruction of a nuisance by self help"). A public nuisance consist of wrongful conduct, and Plaintiffs' Abatement Plan is not directed towards addressing Defendants' conduct. *See infra* Conclusions of Law ¶¶ 133–145.

131. Plaintiffs have not identified any federal court decision that has ordered as an equitable remedy the relief Plaintiffs seek here—*i.e.*, an award of money alone, not adjunct to an injunction, and in principal part for medical treatment (*i.e.*, classic damages). Like the other state cases relied upon by Plaintiffs, *People v. ConAgra Grocery Prod. Co.*, 17 Cal. App. 5th 51, 227 Cal. Rptr. 3d 499 (Ct. App. 2017) does not address federal equity jurisdiction. In *ConAgra*, the California state court applied California law, but state law cannot define or expand the remedies available to a federal court. *See Guaranty Trust Co. v. York*, 326 U.S. at 106; *Sonner*, 971 F.3d at 841.

132. Accordingly, the Court lacks power to award the relief sought by Plaintiffs.

B. Plaintiffs' Abatement Plan Does Not Address Defendants' Conduct But Rather Seeks Recovery for Harms from Opioid Abuse and Addiction.

133. Even if West Virginia law defined the federal court's power to award equitable relief, West Virginia law does not authorize the relief sought by Plaintiffs.

134. Under West Virginia law, a public nuisance consists of wrongful ***conduct***. *See Kermit Lumber*, 200 W. Va. at 245 n.28, 488 S.E.2d at 925 n.28 (public nuisance is "the ***doing of or the failure to do something*** that injuriously affects the safety, health, or morals of the public, or works some substantial annoyance, inconvenience, or injury to the public[.]"); *see also Pope*, 138 W. Va. at 226, 75 S.E.2d at 589 (explaining that "[p]ublic nuisances always arise out of unlawful ***acts***" and evaluating the defendant's

conduct to assess whether the transportation of explosives was a nuisance); *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d at 96 (applying West Virginia law and explaining that a "public nuisance is created" when "a defendant's ***conduct*** 'unlawfully operates to hurt or inconvenience an indefinite number of persons'" (quoting *Duff v. Morgantown Energy Assocs.*, 187 W.Va. 712, 421 S.E.2d 253, 257 (1992))).

135. The conclusion that abatement must address conduct rather than the harms created by a public nuisance is consistent with black-letter tort law, which makes clear that "liability must be based upon ***conduct*** which is socially unreasonable." Prosser & Keeton on Torts ch. 1, § 1, p. 6; see also Dobbs et al., The Law of Torts (2d ed. sup. 2020), § 1 ("A tort is ***conduct*** that amounts to a legal wrong and that causes harm for which courts will impose civil liability."); *Mullins v. Hinkle*, 953 F. Supp. 744, 749 (S.D. W. Va. 1997) ("A claim of tort requires ***conduct*** causing harm and is completed when the harm occurs.").

136. Plaintiffs cite a number of cases to support their contention that an "act or condition" may be a public nuisance. But in each of those cases, the court defined the nuisance at issue as the actionable conduct.

a. In *Martin v. Williams*, 141 W. Va. 595, 611, 93 S.E.2d 835, 844 (1956), the court held that the operation of a used car lot in a residential neighborhood was a nuisance, and in that context stated that a "condition is a nuisance when it clearly appears that enjoyment of property is materially lessened, and physical comfort of persons in their homes is materially interfered with thereby." *Id.* at 844. The "condition" creating the nuisance and the "condition" subject to abatement was the defendant's conduct—the operation of its business. *See id*. ("[T]he carrying on of such business in such locality becomes a nuisance.").

b. In *Burch*, the court held that "nuisance is the unreasonable, unusual, or unnatural ***use*** of one's property so that it substantially impairs the right of another to peacefully enjoy his or her property." 220 W. Va. at 450, 647 S.E.2d at 886.

c. In *Hendricks*, the court held "that the evidence presented clearly does not demonstrate that the water well is an unreasonable ***use*** of land and, therefore, does not constitute a private nuisance." 181 W. Va. at 36, 380 S.E.2d at 203.

d. In *Duff*, the court explained that "[i]t does not clearly appear from the record that ***conducting the proposed trucking*** in this locality will be unreasonable or that it is reasonably certain to cause serious harm" but that "the proposed trucking may constitute a public nuisance once it is operational." 421 S.E.2d at 262.

137. Under West Virginia law, Plaintiffs' remedy is limited to "elimination of hazards to public health and safety" and "abate[ment]" of the alleged public nuisance. *See* W. Va. Code §§ 7-1-3kk (granting county commissions limited authority); W Va. Code §§ 8-12-5(23) (same for municipalities).

138. "Under the traditional definition of abatement, nuisance claims seek court intervention to ***require one party to stop doing something*** that affects another…. Examples of

conduct that may be enjoined include merry-go-rounds, and loud singing, talking, dancing, and opening and shutting doors." *State ex rel. AmerisourceBergen Drug Corp. v. Moats*, 859 S.E.2d 374, 389–90 (W. Va. 2021) (Armstead, J., concurring in part) (internal citations omitted)).

139. Equitable abatement has historically been limited to an ***injunction*** designed to eliminate the allegedly tortious conduct or, in certain environmental nuisance cases, an injunction to remove the contaminant from the environment. *See, e.g.*, *Duff*, 187 W. Va. at 716, 421 S.E.2d at 257 (noting that "courts generally grant injunctions to abate existing nuisances"); *see also, e.g.*, *Bansbach v. Harbin*, 229 W. Va. 287, 292, 728 S.E.2d 533, 538 (2012) (referring to injunction requiring party to halt activity as abatement); *Burch*, 220 W. Va. at 456, 647 S.E.2d at 892–94 (using abatement and injunctive relief interchangeably, and holding that "an unsightly activity may be abated when it occurs in a residential area and is accompanied by other nuisances"); *Berkeley Cty. Comm'n v. Shiley*, 170 W. Va. 684, 686, 295 S.E.2d 924, 926 (1982) (discussing state and local officials' power under state law to bring suits seeking injunctions to "abate" nuisances); *Martin*, 141 W. Va. at 605, 93 S.E.2d at 841 ("Mandatory injunctions are awarded for the abatement of nuisances more frequently than for other purposes."); *Fellows v. City of Charleston*, 62 W. Va. 665, 59 S.E. 623, 625 (1907) ("The town has power to enforce its ordinance, and, if necessary for the abatement or removal of the [public] nuisance, [and] may remove or destroy the thing creating the nuisance[.]"); *Woods v. Cottrell*, 55 W. Va. 476, 47 S.E. 275, 277 (1904) (a public nuisance "may be abated as part of the judgment, and the thing with which the nuisance is done may be destroyed").

140. As the Supreme Court of Appeals of West Virginia has recognized, the distinction between "abatement of nuisances and recovery of damages for injuries occasioned by wrongful acts, constituting nuisances," is both "apparent" and "vast." *McMechen v. Hitchman-Glendale Consol. Coal Co.*, 88 W. Va. 633, 107 S.E. 480, 482 (1921); *see also* Prosser and Keeton, The Law of Torts, § 631 (5th ed. 1984) (referring to the "fundamental distinction between entitlement to damages and entitlement to abatement of the nuisance").

141. Damages, unlike abatement, are directed to compensating the plaintiff for "the cost[s] of eliminating the nuisance effects". Dobbs, I Law of Remedies § 5.7(3).

142. Plaintiffs, however, are not seeking to "abate"—*i.e.*, enjoin or stop—the nuisance. Instead, Plaintiffs are seeking remuneration for the costs of treating downstream harms of opioid use and abuse. *See supra* Findings ¶¶ 221–225; *see also* Mem. of Law in Support of Defs.' Mot. for Judgment on Partial Findings Regarding Abatement (ECF No. 1451) at 4–6,13–14. Those costs have no direct relation to any of Defendants' alleged misconduct.

    a. 98.85% of Plaintiffs' proposed Abatement Plan is directed to treating or otherwise addressing drug use and addiction, ***not*** any of Defendants' conduct. *See supra* Findings ¶ 221(c).

b. Only one element of the Abatement Plan—accounting for approximately 0.0014% of the total cost—is even arguably addressed to the volume of prescription opioids in Cabell/Huntington. *See supra* Findings ¶ 222.

c. Plaintiffs' proposed Abatement Plan is intended to address the opioid epidemic as a whole, rather than addressing Defendants' conduct. *See supra* Findings ¶ 225.

143. It is immaterial that Plaintiffs have now termed their proposed relief "abatement damages," a term that finds no support in West Virginia law. The United States Supreme Court has cautioned that with "lawyerly inventiveness," any claim seeking legal relief can be phrased as one seeking equitable relief. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 211 n.1 (2002). Courts appropriately focus on the substance of the claim asserted, not labels affixed by counsel. *See, e.g.*, *Gilbert v. City of Cambridge*, 932 F.2d 51, 57–58 (1st Cir. 1991). Any such monetary award—whether styled as damages or "abatement damages"—is not properly an element of equitable abatement relief.

144. Plaintiffs have waived any claim for damages. *See supra* Conclusions ¶ 123. Yet their Abatement Plan overwhelmingly seeks payment for the treatment of opioid addiction and abuse, and the downstream harms that flow from opioid abuse and addiction. *See supra* Findings ¶¶ 221–222. These are forms of future damages, which are barred by Plaintiffs' waiver of damages. And they are not properly abatement of the claimed nuisance, for the reasons set forth above.

145. Plaintiffs have compared this case to *Kermit Lumber* and environmental nuisance cases more generally. But even under *Kermit Lumber*, Plaintiffs' remedy fails. There, the relevant conduct was the depositing of arsenic "on the Kermit Lumber business site in amounts above the regulatory limits," which then "flow[ed] into the Tug Fork River." 200 W.Va. at 245. Recognizing that "[t]he object of a public nuisance action is to abate or stop the harm to the public health, safety, and the environment," the court held on the facts of that case that the nuisance "continue[d] ***until the hazardous waste is removed***." *Id.* at 245 n.29. The abatement in *Kermit Lumber* therefore consisted of removing the excessive or above-limits arsenic from the environment. *See id.* at 245. Tellingly, *Kermit Lumber* did not hold that the plaintiff could recover, as abatement, for downstream harms to the community resulting from the contamination in the Tug River, such as treatment for injuries from those who consumed or came in contact with contaminated water.

C. Plaintiffs' Abatement Plan Seeks Recovery for Costs Arising from Future Addiction and Abuse Without Proof of any Future Conduct by Defendants.

146. Plaintiffs' Abatement Plan consists in very large part of treatment and other medical expenses and programs for Cabell/Huntington residents who are ***not now addicted*** to opioids but ***will***, according to Plaintiffs, become addicted at some point in the future. *See* Mem. of Law in Support of Defs.' Mot. for Judgment on Partial Findings Regarding Abatement (ECF No. 1451) at 14–19. *See also supra* Findings ¶¶ 252–256.

147. Under West Virginia law, where "the nuisance of which the plaintiffs complain is prospective, the plaintiffs bear a heavy burden of proving that harm is reasonably certain to result from" the defendant's conduct. *Duff*, 187 W. Va. at 721, 421 S.E.2d at 262. In particular, "[t]he plaintiff seeking the injunction to abate the prospective nuisance bears the burden of proving that the proposed conduct will constitute a nuisance 'beyond all ground of fair questioning.'" *Id.* at 717 n.9, 258 n.9; *see also* Memorandum Opinion and Order (ECF No. 1248) at 10 (quoting *Duff*).

148. Plaintiffs failed to present any evidence that Defendants' allegedly wrongful conduct is responsible for the ***future*** addiction of different Cabell/Huntington residents, and therefore have failed to satisfy their "heavy burden" in order to recover for a prospective nuisance under West Virginia law.

149. Moreover, the record evidence reflects that Defendants' ***current*** conduct does not constitute a public nuisance in Cabell/Huntington. *See supra* Conclusions of Law ¶¶ 47–51. Accordingly, under the exacting legal standard set forth in *Duff*, Defendants cannot be held liable for current and future opioid addiction and abuse in Cabell/Huntington.

D. The "Abatement" Plan Would Result in an Improper Windfall Recovery for Cabell/Huntington.

150. It is well established that federal courts sitting in equity may not award more than is necessary to make a plaintiff whole. *See, e.g.*, *Pender v. Bank of Am. Corp.*, 736 F. App'x 359, 371 (4th Cir. 2018) ("[C]ourts and commentators have cautioned against awarding a plaintiff equitable relief … to the extent doing so would amount to a windfall or penalize a defendant."); *Am. Mortg. Network, Inc. v. Shelton*, 486 F.3d 815, 820 (4th Cir. 2007) (concluding that counterclaimants' requested relief, which amounted to a "windfall" recovery, "offends traditional notions of equity"); *Szedlock v. Tenet*, 139 F. Supp. 2d 725, 736 (E.D. Va. 2001) (holding that "equitable principles require an appropriate offset to ensure that plaintiff is ***only made whole*** and is ***not awarded a windfall***."), *aff'd*, 61 F. App'x 88 (4th Cir. 2003); *see also Marshall v. City of Vicksburg*, 82 U.S. 146, 149 (1872) ("Equity never, under any circumstances, lends its aid to enforce a forfeiture or penalty, or anything in the nature of either.").

151. The Court, sitting in equity, must take account of the fact that drug addiction and drug treatment programs are almost entirely paid for by the federal and state government and not by Cabell County or Huntington, that there are extensive opioid-related programs and services already being offered in Cabell/Huntington that cover the same areas of services proposed by Plaintiffs' Abatement Plan, and that Plaintiffs' proposed remedy fails to take into account any unmet need for opioid treatment services in the Cabell/Huntington community. *See supra* Findings ¶¶ 229–233.

152. The evidence demonstrates that Plaintiffs have already achieved the goals of the proposed Abatement Plan. *See supra* Findings ¶¶ 234–238.

153. Many of these drug addiction and drug treatment programs are paid for through Medicaid payments that go directly to the participants in these programs. *See supra* Findings ¶ 245–247.

154. Other of these drug addiction and drug treatment programs, and various law enforcement programs directed at drug activity, are paid for by grant money awarded to Cabell or Huntington by grants from the federal and state government, or other grant-based funding. *See supra* Findings ¶ 231.

155. Cabell and Huntington are not entitled to recover spending for programs that are paid for either directly or indirectly by the federal and state government and not by them.

156. Plaintiffs are not entitled to recover a remedy for programs they have not paid for and will not pay for in the future.

157. The collateral source rule, *see Kenney v. Liston*, 233 W. Va. 620, 760 S.E.2d 434 (2014), does not apply to a claim for equitable relief and does not preclude the Court, sitting in equity, from taking account of the fact that Plaintiffs are seeking a remedy that includes (a) payments by Medicare and other health insurers for drug treatment programs, which Plaintiffs do not pay for, and (b) programs that are funded by the federal and state government, not Plaintiffs. *See* Memorandum Opinion and Order (ECF No. 1281).

E. Plaintiffs' Abatement Plan Fails for Lack of Sufficient Proof.

158. The Court concludes that Plaintiffs have failed to prove their entitlement to an abatement remedy.

159. Where there is a wholesale failure of proof as to a plaintiff's entitlement to a remedy, judgment is warranted as a matter of law. *See, e.g.*, *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."); *Weisgram v. Marley Co.*, 528 U.S. 440, 445 (2000) (affirming conclusion that defendant's motion for judgment as a matter of law should have been granted where testimony of plaintiffs' expert witness, which was the sole evidence supporting plaintiff's product defect claim, was "speculative and not shown to be scientifically sound" and therefore not properly admitted).

160. Plaintiffs have not presented sufficient evidence in support of their entitlement to their requested form of abatement relief.

a. The Abatement Plan takes no account of the many existing opioid-related programs and services already being provided in Cabell/Huntington, *see supra* Findings ¶¶ 226–228;

b. There is no evidence of concrete, unmet needs in the Cabell/Huntington community for opioid-related programs and services, *see supra* Findings ¶¶ 229–233;

c. The evidence shows that the Cabell/Huntington community has already reached the goals of the Abatement Plan, *see supra* Findings ¶¶ 234–238;

d. The population inputs in the Abatement Plan are inflated and unreliable, *see supra* Findings ¶¶ 260–270;

e. The cost projections and overall treatment figures included in Abatement Plan are inflated and unreliable, *see supra* Findings ¶¶ 279–281; and

f. Dr. Alexander deviated from his own methodology in developing the Abatement Plan, rendering his testimony here unreliable, *see supra* Findings ¶¶ 282–283.

F. Plaintiffs Cannot Remedy the Failures of their Abatement Plan by Seeking a "Court-Supervised" Trust Fund.

161. The Court concludes that Plaintiffs cannot remedy the myriad legal and factual failures of their Abatement Plan by seeking a "Court-supervised" trust fund.

162. *First*, there is no evidence that third parties need additional funds to run the many programs that are already in place in Cabell/Huntington to address the opioid crisis. On the contrary, there is ample record evidence that funding for the largest elements of the Abatement Plan—namely medical treatment and foster and adoption services—is both sufficient and readily available. *See supra* Findings Part XIV.

163. *Second*, creating a Court-supervised trust fund to disburse funds to non-parties that have made no showing of any injury caused by Defendants for programs not run or funded by Plaintiffs would be contrary to fundamental tort principles of causation and injury.

164. *Third*, disbursing funds to non-parties that are controlled by the State of West Virginia—for example, Marshall University,[11] one of the programs specifically identified by Plaintiffs to receive these funds, Opp. at 18—would result in a double windfall for the State, which has already received its own settlement funds for claims on this precise issue. *See infra* Conclusions of Law ¶¶ 188–195; *see also* Ex. DEF-WV-02150 (settlement agreement between the State of West Virginia and McKesson Corporation); Ex. DEF-WV-02151 (settlement agreement between the State of West Virginia and AmerisourceBergen Drug Corporation); Ex. DEF-WV-02152 (settlement agreement between the State of West Virginia and Cardinal Health). Such a windfall would offend "equitable principles" that require that *Plaintiffs* be made whole and no more. *Szedlock*, 139 F. Supp. 2d at 736.

[11] *See, e.g.*, W. Va. Code § 18-2-13d ("[T]he state educational institution located at Huntington, West Virginia, previously known as Marshall College shall, after the effective date of this section, be known as Marshall University, … and this university shall remain under the supervision and control of the state board of education.").

165. *Fourth*, there is no evidence concerning how the fund would be administered or overseen, who would be eligible for payments from the fund and how that would be determined, or what would happen with unused funds.

166. Plaintiffs cite to *People v. ConAgra Grocery Prods. Co.*, 227 Cal. Rptr. 3d 499 (Cal. Ct. App. 2017), as an example of a Court-supervised abatement fund. But, far from supporting Plaintiffs' position, *ConAgra* demonstrates precisely why Plaintiffs' Abatement Plan is improper. In *ConAgra*, the plaintiffs alleged that the defendants' improper marketing and sale of lead paint for use in homes constituted a public nuisance. *ConAgra Grocery Prod. Co.*, 227 Cal. Rptr. 3d at 529. The evidence reflected that lead paint used in homes resulted in lead poisoning and caused developmental and health defects, including brain damage in exposed children. *Id.* at 514–16. After finding a public nuisance under California law, the court ordered the nuisance abated. *Id.* at 569. Importantly, the abatement consisted of ***removing the lead paint*** from the homes, ***not*** medical or other treatment for harms resulting from exposure to the lead paint. *Id.* As the court stated, "the abatement account would be utilized ***not to recompense anyone for accrued harm*** but solely to pay for the prospective removal of the hazards defendants had created"—*i.e.*, removal of the lead paint. *Id.* at 569.

167. Here, the fund that Plaintiffs seek to establish would fund primarily treatment programs for downstream harms caused by opioid addition and abuse, *see supra* Findings ¶¶ 133–145—*i.e.*, precisely the type of funding that was ***not*** permitted from the abatement account in *ConAgra*.

IX. Apportionment / No Joint and Several Liability

168. Plaintiffs attempt to avoid their failures of proof on proximate causation and remedy by invoking the doctrine of joint and several liability.

169. As an initial matter, the doctrine of joint and several liability relates to the apportionment of liability ***between defendants*** who have been found liable for actionable conduct, and ***does not*** cure the fatal defects in Plaintiffs' legal case, including the lack of proximate causation and lack of entitlement to any cognizable form of abatement relief. *See, e.g.*, Reply Mem. in Support of Defs.' Mot. for Judgment on Partial Findings Regarding Abatement (ECF No. 1485) at 15–18.

170. And, in any event, Defendants are not jointly and severally liable for the entirety of the opioid epidemic in Cabell/Huntington.

171. West Virginia law makes clear that joint and several liability does not apply in this case. As the Supreme Court of Appeals of West Virginia explained, "[t]wo or more tort-feasors acting independently, without concert, collusion, or pursuit of a common design, in the perpetration of like wrongful acts at the same time, working like injury to the same subject, are not jointly liable for injury subsequently resulting to any person from combination of the consequences of such wrongful acts by the operation of natural causes." Syl. Pt. 1, *Farley v. Crystal Coal & Coke Co.*, 85 W. Va. 595, 595, 102 S.E. 265, 265 (1920); *id.* (holding that, absent concerted action, different coal mining

companies cannot be held jointly and severally liable for pollution of a river into which they all discharged); *accord West v. Nat'l Mines Corp.*, 168 W. Va. 578, 589, 285 S.E.2d 670, 678 (1981).

172. Plaintiffs have not presented evidence of concerted action or a civil conspiracy.

a. "[A] civil conspiracy is a combination of two or more persons by concerted action to accomplish an unlawful purpose or to accomplish some purpose, not in itself unlawful, by unlawful means." *Dixon v. Am. Indus. Leasing Co.*, 162 W. Va. 832, 834, 253 S.E.2d 150, 152 (1979). "[A] civil conspiracy must be based on some underlying tort or wrong." *O'Dell v. Stegall*, 226 W. Va. 590, 625, 703 S.E.2d 561, 596 (2010).

b. Plaintiffs have not presented evidence of collusion or concerted action between Defendants—who are business competitors.

c. Nor have Plaintiffs sufficient evidence of collusion or concerted action between any Defendant and any other parties, including the manufacturers of opioid medicines or any of the severed co-defendants.

173. It is inappropriate to lump together as a single alleged harm the myriad distinct injuries, stemming from myriad distinct actors and causes, that constitute the "opioid crisis" in Cabell/Huntington. Accordingly, even assuming *arguendo* that Defendants are liable at all, they cannot be jointly and severally liable for the entirety of the "opioid crisis" in Cabell/Huntington.

a. It is a fundamental principle of law that a defendant can be liable for only injuries that it caused. *See, e.g.*, *Univ. of Texas Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346 (2013) ("Causation in fact—*i.e.*, proof that the defendant's conduct did in fact cause the plaintiff's injury—is a standard requirement of any tort claim."); *Frank Krasner Enterprises, Ltd. v. Montgomery Cty., MD*, 401 F.3d 230, 234 (4th Cir. 2005) ("To have a claim heard in federal court, a plaintiff must establish … a causal connection between the injury and the conduct complained of.").

b. Where a plaintiff suffers multiple discrete injuries, a defendant may be liable only for the injuries that the defendant played a role in causing.

c. Thus, for example, Defendants may not be jointly and severally liable for harms flowing from the trafficking of illegal drugs (such as heroin and illicit fentanyl) into Cabell/Huntington by non-party drug dealers.

174. Plaintiffs may not recover for opioid-related losses that do not flow from Defendants' allegedly wrongful conduct. Defendants may not be held liable merely for the lawful operation of their pharmaceutical distribution business, but only for *wrongful* conduct. *See, e.g.*, *Sharon Steel Corp.*, 175 W. Va. at 483, 334 S.E.2d at 620.

175. Under the legal maxim of *damnum absque injuria*, mere loss—*damnum*—is not enough to support a legal cause of action—"there must also be *injuria*," meaning "something

done against the right of the party." *W. Virginia Transp. Co. v. Standard Oil Co.*, 50 W. Va. 611, 40 S.E. 591, 592 (1901); *accord Bolling v. Clay*, 150 W. Va. 249, 257, 144 S.E.2d 682, 688 (1965) (loss that is "not attributable to negligence or misconduct on the part of another is damnum absque injuria").

a. Where a portion of an injury is *damnum absque injuria*, that portion must be excluded from any liability. *Shenandoah Valley R. Co. v. Shepherd*, 26 W. Va. 672, 681, 684–85 (1885) (setting aside jury verdict where jury awarded $1,000 in damages, because as a matter of law, any verdict greater than $150 must have improperly included injuries that were *damnum absque injuria*); Restatement (Third) of Torts § 26 (apportionment of liability is appropriate "when the parties caused one part of the damages and ***nontortious conduct*** caused another part").

b. Thus, for example, it is undisputed that some Cabell/Huntington residents became addicted after taking the medicines as appropriately prescribed by their doctors to meet a legitimate medical need. Those harms are not attributable to the negligence or misconduct of anyone; therefore, Defendants cannot be held liable for them.

176. Under West Virginia law, fault "must be ascertained in relation to ***all*** of the parties whose negligence contributed to the accident, and not merely those defendants involved in the litigation." *Bowman v. Barnes*, 168 W. Va. 111, 124, 282 S.E.2d 613, 621 (1981); *accord Modular Bldg. Consultants of W. Virginia, Inc. v. Poerio, Inc.*, 235 W. Va. 474, 484–85, 774 S.E.2d 555, 565–66 (2015) ("[W]here issues of plaintiff's comparative negligence and joint tortfeasors converge, the jury should assess the fault of all parties.").

177. Even assuming *arguendo* that the entirety of the "opioid epidemic" in Cabell/Huntington constitutes a single injury, the Court holds as a matter of law that any such injury is divisible and capable of apportionment. *See Grant Thornton, LLP v. FDIC*, 694 F. Supp. 2d 506, 525 (S.D.W. Va. 2010), *rev'd on other grounds*, 435 F. App'x 188, 203 (4th Cir. 2011); *see also Courtland Co., Inc. v. Union Carbide Corp.*, 2020 WL 5047131, at *18 (S.D.W. Va. Aug. 26, 2020) ("finder of fact" in nuisance action may "determine the extent to which [plaintiff] may recover for each alleged harm based on the proportion that each [defendant] may have contributed to such harm"); *Edmonds v. Compagnie Generale Transatlantique*, 443 U.S. 256, 260 n.8 (1979) (joint and several liability "principles, of course, are inapplicable where the injury is divisible and the causation of each part can be separately assigned to each tortfeasor" (citing Restatement (Second) Torts §§ 433A(1) & 881)).

a. "As a practical matter, many nuisances are capable of apportionment among two or more persons who contribute to them, because a reasonable basis can be found for dividing the harm done on the basis of the extent of the contribution of each party." Restatement (Second) of Torts § 840E, cmt. a, b (1979). This rule "applies to both public and private nuisances." *Id.*

b. In performing an apportionment, the Court must consider both causation (*i.e.*, whether a particular defendant was a cause of a particular injury) and comparative

responsibility (*i.e.*, the relative culpability of different contributors to an individual injury). *See* Restatement (Third) of Torts § 26 (2000), cmt. a.

c. As this Court has previously recognized, "[t]he fact that the magnitude of each indivisible component part cannot be determined with precision does not mean that the damages are indivisible. All that is required is a reasonable basis for dividing the damages." *Grant Thornton, LLP*, 694 F. Supp. 2d at 525 (quoting Restatement (Third) of Torts § 26 (2000)).

178. The Court rejects any suggestion that an apportionment is inappropriate here because Plaintiffs seek only the "equitable remedy" of abatement.

a. A public nuisance claim sounds in tort. As noted above, a fundamental principle of all tort claims is that a defendant may be liable only for injuries that the defendant played some role in causing. This remains so irrespective of the remedy sought by Plaintiffs.

b. Moreover, the "essence of equity jurisdiction" is the power of the court "to mould each decree to the necessities of the particular case." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). The formation and application of equitable remedies therefore turns on the degree to which the remedy "sought is essential to the ends of justice." *First Am. Title Ins. Co. v. Firriolo*, 225 W. Va. 688, 696, 695 S.E.2d 918, 926 (2010); *see also* Dobbs on Remedies, § 2.1 ("Discretion as to equitable remedies goes beyond the power to deny relief; it extends as well to the power of shaping relief, determining its extent, scope, and particular incidents."). Thus, to the extent that the Court is called upon here to craft an equitable remedy, the Court holds that equity and fairness requires an apportionment of liability. *E.g.*, *Modular Bldg. Consultants of W. Virginia, Inc.*, 235 W. Va. at 485, 774 S.E.2d at 566 (requiring apportionment for reasons of "simple fairness"); *Landis v. Hearthmark, LLC*, 232 W. Va. 64, 75, 750 S.E.2d 280, 291 (2013) (requiring apportionment to non-party "[b]ased upon equitable principles of fairness").

179. There is a reasonable basis for dividing the harm underlying Plaintiffs' claims based on the relative contributions of Defendants, Plaintiffs, severed defendants, and non-parties.

180. The parties (other than Defendants in this trial) who played a role in causing Plaintiffs' alleged injuries, and to whom the Court apportions a share of the overall liability, are:

a. Opioid manufacturers, *see supra* Findings ¶¶ 11–13, 25;

b. Doctors, *see supra* Findings ¶¶ 8, 40–45, 51;

c. Pharmacies, hospitals, and other dispensers, *see supra* Findings ¶¶ 10, 48–49, 51;

d. Illegal drug traffickers and dealers, *see supra* Findings ¶¶ 169, 171–173;

e. Illicit drug users, *see supra* Findings ¶¶ 176;

f. Individuals who diverted prescription opioids, *see supra* Findings ¶¶ 103, 113, 115;

g. Individuals who used diverted prescription opioids, *see supra* Findings ¶¶ 115;

h. FDA, *see supra* Findings ¶¶ 20, 97;

i. DEA, *see supra* Findings ¶¶ 26(d), 45(d)–(e), 72, 80–81, 85;

j. West Virginia Board of Medicine, *see supra* Findings ¶¶ 22(f)–(g), 26(d), 27;

k. West Virginia Board of Pharmacy, *see supra* Findings ¶ 85;

l. Joint Commission, *see supra* Findings ¶¶ 24;

m. Health insurers, *see supra* Findings ¶¶ 54–63;

n. Plaintiffs; and

o. Other wholesale distributors—including but not limited to Miami-Luken, Inc., which serviced the A Plus Care Pharmacy—that collectively accounted for more than 25% of the wholesale distributions of prescription opioids into Cabell/Huntington, *see* Ex. P-44711 at .00001.

X. West Virginia's Non-Party Fault Statute

181. Taking account of the other actors involved in causing the opioid crisis in Cabell/Huntington, Defendants' fault for Plaintiffs' injury is *de minimis* pursuant to W. Va. Code Ann. Section 55-7-13d(a)(1) because of the fault of nonparties to this case. *See supra* Findings ¶¶ 217–218; *see also supra* Conclusions of Law ¶¶ 180.

182. Pursuant to West Virginia's contribution statute, "[i]n assessing percentages of fault, the trier of fact shall consider the fault of all persons who contributed to the alleged damages regardless of whether the person was or could have been named as a party to the suit." W. Va. Code Ann. § 55-7-13(d)(1); *see also Modular Bldg. Consultants of W. Virginia, Inc.,* 235 W. Va. at 486 n.4, 774 S.E.2d at 567 n.4 (noting that the contribution statutes "in fact do purport to fully occupy the field of comparative fault and the consideration of 'the fault of parties and nonparties to a civil action[.]"); *Stratford v. Brown*, 2018 WL 5649901, at *4 (S.D.W. Va. Oct. 31, 2018) ("Under West Virginia law, the fault of parties and nonparties alike may be considered when the trier of fact is assessing percentage of fault.").

183. In "all actions involving fault of more than one person," for purposes of allocating fault the Court "may determine that two or more persons are to be treated as a single person." W. Va. Code § 55-7-13d(a)(6).

184. The statutory language is undeniably broad, applying "[i]n any action based on tort or any other legal theory seeking damages." W. Va. Code § 55-7-13a(b). Either circumstance applies to Plaintiffs' claim here.

185. First, West Virginia law considers public nuisance a tort. *Kermit Lumber*, 200 W.Va. at 245 n.29, 488 S.E.2d at 925 n.29.

186. Second, Plaintiffs are seeking money damages in the form of future costs. Plaintiffs' description of their proposed remedy as "abatement damages," as opposed to "damages" does not remove Plaintiffs' claim from West Virginia's contribution statute. Future damages are a component of overall compensatory damages. *See, e.g.*, Syl. Pt. 9, *Jordan v. Bero*, 158 W. Va. 28, 29, 210 S.E.2d 618, 623 (1974) ("The permanency or future effect of any injury must be proven with reasonable certainty in order to permit a jury to award an injured party future damages.").

187. The West Virginia Supreme Court's recent decision in *State ex rel. AmerisourceBergen Drug Corp. v. Moats*, 859 S.E.2d 374 (W. Va. 2021), is not to the contrary. In that case, the Supreme Court stated that "injunctive relief is frequently the means by which a public nuisance is prevented or abated," and recognized that there is substantial case law in support of the proposition that where, as here, a plaintiff requests a payment of money, the claims are legal rather than equitable. *See id.*at 384–85. Ultimately, the Supreme Court ruled only that "we cannot say ***now*** that the Panel's ruling—that Plaintiffs' public nuisance claims are not legal claims for damages … that are subject to the [non-party fault statute]—is so clear-cut, or so plainly in contravention of a clear legal mandate as to merit issuance of the extraordinary remedy of prohibition." *Id.* at 385. The Supreme Court ***did not*** resolve the question of whether the plaintiffs' public nuisance claims in that action or any other are legal or equitable under West Virginia law, but rather left that determination for a future appeal.[12]

XI. Res Judicata and Release

188. The State of West Virginia, acting through the West Virginia Attorney General's Office, previously brought suit against AmerisourceBergen, Cardinal Health and McKesson for opioid-related harms.

189. The State settled its lawsuit against AmerisourceBergen and Cardinal Health in 2012. At that time, the State separately released all claims "which [it] has asserted or could have asserted on its own behalf or in its *parens patriae* capacity that the State now has or may have in the future against [AmerisourceBergen and Cardinal Health] growing out of, relating to, or concerning" the State's lawsuit. It did so for "each and every" State agency, department and instrumentality, including "any agency, person, or other entity claiming by or through them or any of them."

190. The State settled its lawsuit against McKesson in 2019. At that time, the West Virginia Attorney General, acting on behalf of "all of the citizens and entities of the State,"

[12] Notably, despite the high legal standard, multiple justices—including Chief Justice Jenkins—authored a partial dissent arguing that the non-party fault statute ***does*** apply to the plaintiff's public nuisance claims because they are legal in nature, and that the Supreme Court should have issued a writ of prohibition enjoining the Panel's order below. *See State ex rel. AmerisourceBergen Drug Corp.*, 859 S.E.2d at 388–92.

entered into a settlement agreement with each Defendant to resolve finally and completely "all claims" that could have been asserted in its litigation against that Defendant "arising out of Defendant's conduct as a distributor of pharmaceuticals in the State of West Virginia."

191. Plaintiffs' claims against AmerisourceBergen, Cardinal Health and McKesson are based on the same misconduct alleged in the State's prior lawsuits against Defendants—namely, alleged misconduct arising out of wholesale pharmaceutical distribution in West Virginia and its constituent counties and municipalities.

192. "[A] suit can be barred by the earlier settlement of another suit in either of two ways: res judicata or release." *Nottingham Partners v. Trans-Lux Corp*., 925 F.2d 29, 31–32 (1st Cir. 1991).

193. Res judicata, or claim preclusion, bars a subsequent suit when (1) there was "a final adjudication on the merits in the prior action"; (2) "the two actions … involve either the same parties or persons in privity with those same parties"; and (3) "the cause of action identified for resolution in the subsequent proceeding either [is] identical to the cause of action determined in the prior action or [is] such that it could have been resolved, had it been presented, in the prior action." *Dan Ryan Builders, Inc. v. Crystal Ridge Dev., Inc.*, 239 W.Va. 549, 560, S.E.2d 519, 530 (2017).

194. For release, "[w]hen a consent judgment entered upon settlement by the parties of an earlier suit is invoked by a defendant as preclusive of a later action, the preclusive effect of the earlier judgment is determined by the intent of the [settling] parties." *Keith v. Aldridge*, 900 F.2d 736, 740 (4th Cir. 1990).

195. The State of West Virginia released Plaintiffs' claims against Defendants.

XII. Resolution of Pending Evidentiary Motions

196. Several evidentiary motions made by the parties remained pending before the Court at the close of evidence. Based on its consideration of the parties' briefing, oral argument (as applicable), and all other relevant materials, the Court hereby rules as follows:

a. McKesson Corporation's Motion to Prohibit Plaintiffs' Improper Use of Testimony of McKesson Witness Nathan Hartle (ECF No. 1298) is GRANTED;

b. Defendants' Motion to Exclude the Rule 30(b)(6) Deposition Testimony of Thomas Prevoznik (ECF No. 1310) is GRANTED;

c. Defendants' Renewed *Daubert* Motion to Exclude the Opinions of James E. Rafalski (ECF No. 1385; *see also* 5/27 Tr. 52:16–57:4 (oral motion)) is GRANTED;

d. Defendants' *Daubert* Motion to Exclude the Opinions of Jakki Mohr (6/11 Tr. 79:3–83:1 (oral motion)) is GRANTED;

e. Defendants' Renewed *Daubert* Motion to Exclude the Opinions of Thomas McGuire (6/17 Tr. at 78:4–82:21 (oral motion)) is GRANTED;

f. Defendants' Renewed *Daubert* Motion to Exclude the Opinions of G. Caleb Alexander (6/29 Tr. at 44:2–49:5 (oral motion)) is GRANTED;

g. Defendants' Renewed *Daubert* Motion to Exclude the Opinions of George Barrett (6/29 Tr. at 209:16–211:13 (oral motion)) is GRANTED;

h. Defendants Motion for Admission of Plaintiffs' Judicial Admissions Concerning Manufacturer Conduct (ECF No. 1462; *see also* 7/12 Tr. at 163:2–164:24 (oral motion)) is GRANTED;

i. Plaintiffs' Motion for Reconsideration of Exclusion of Declaration of Defendant Cardinal Health, Inc. on Confidential Trade Secret Status of its ACROS [sic] Data (ECF No. 1397) is DENIED;

j. Plaintiffs' Motion to Take Judicial Notice (ECF No. 1433) is:

    i. GRANTED insofar as the Court will take judicial notice of the documents identified at ECF Nos. 1433-5, 1433-6, 1433-7, 1433-12; and

    ii. otherwise DENIED.

k. Plaintiffs' Trial Memorandum Regarding Admissibility of P-00045, the Cegedim Dendrite Audit of Cardinal Health's Suspicious Order Monitoring System (ECF No. 1435), which seeks reconsideration of the Court's order excluding P-00045, is DENIED;

l. Plaintiffs' Trial Memorandum Regarding Admissibility of Letters from the DOJ/DEA to McKesson (ECF No. 1437), which seeks reconsideration of the Court's order excluding P-00018, P-00199, P-00121, and P-00122, is DENIED.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

APPENDIX A: ADDITIONAL WITNESS-SPECIFIC FINDINGS OF FACT

ADDITIONAL WITNESS-SPECIFIC FINDINGS OF FACT[13]

I. Robert "Corey" Waller

1. Corey Waller is a physician and Associate Professor at Michigan State University. *See* 5/4 Tr. (Waller) at 11:17–23, 12:15–25.

2. Dr. Waller was qualified as an expert in the fields of neuroscience, addiction, and pain. *See* 5/4 Tr. (Waller), at 20:3–5.

3. Dr. Waller did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

4. Dr. Waller did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

II. David Courtwright

5. David Courtwright is a historian who taught at the University of North Florida and other institutions before retiring in 2019. *See* 5/5 Tr. (Courtwright), at 10:23–4.

6. Dr. Courtwright was qualified as an expert in the history of opiate use and abuse in drug policy. *See* 5/5 Tr. (Courtwright) at 18:1–3.

7. Dr. Courtwright testified only to events and activities prior to the passage of the Controlled Substances Act in 1970. *See generally* 5/5 Tr. (Courtwright) at 10:6–44:15.

8. Dr. Courtwright did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

9. Dr. Courtwright did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

III. Rahul Gupta

10. Rahul Gupta served as Physician Director, Local Health Officer, and Executive Director of the Kanawha-Charleston Health Department from March 2009 to December 2014. *See* 5/5 Tr. (Gupta) at 47:2–5. Dr. Gupta also served as the Commissioner for the Bureau of Public Health and Human Resources and the State Health Officer for the State of West Virginia from January 2015 to November 2018. *See id.* at 47:9–12.

[13] This appendix contains additional witness-specific findings of fact concerning Plaintiffs' fact and expert witnesses and Defendants' non-company witnesses. Findings of fact concerning Defendants' company witnesses can be found in Defendants' company-specific sections. *See generally* Appendix B–D.

11. Dr. Gupta did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

12. Dr. Gupta did not offer any testimony concerning whether Defendants caused any harm to the Huntington or Cabell County resulting from legal or illegal opioids.

13. During his years heading the State Board of Health, Dr. Gupta oversaw the preparation of a series of reports analyzing the opioid crisis and recommending steps that could be taken to address the crisis. The reports did not make any recommendations concerning Distributors. He asserted that his reports did not address Distributors because they are not within the purview of the Bureau of Public Health and that the Bureau of Public Health does not regulate Distributors, *see, e.g.*, 5/6 Tr. (Gupta) at 11:9–19, but the reports do make recommendations concerning numerous entities that do not fall within the purview of the Bureau of Public Health, including the Department of Corrections, the Board of Pharmacy, the judicial branch, and the state legislature. *See id.* at 11:24–13:24.

14. Dr. Gupta is a retained expert for the plaintiffs in the West Virginia state MLP opioid cases. *See* 5/6 Tr. (Gupta) at 38:8–10. Dr. Gupta is paid approximately $500 per hour for his work as a retained expert in the state MLP opioid cases. *See id.* at 38:13–17.

15. In 2018, Dr. Gupta spoke at an "Opioid Crisis Summit" hosted by plaintiffs' law firms. *See* 5/6 Tr. (Gupta) at 41:24–42:10.

IV. Connie Priddy

16. Connie Priddy is the Director of Quality Compliance at Cabell County EMS and the Program Coordinator for the Huntington Quick Response Team ("QRT"). *See* 5/6 Tr. (Priddy), at 182:23–183:5. Ms. Priddy is also a licensed nurse. *See id.* at 184:20–185:1.

17. Ms. Priddy did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

18. Ms. Priddy did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

19. Ms. Priddy did not offer any testimony that existing treatment options in Cabell/Huntington lacked capacity. Instead, she testified that "most generally" the Huntington Quick Response Team is able to find a treatment bed for every person in need. *See* 5/6 Tr. (Priddy), at 231:14–16.

20. Ms. Priddy is unaware of anyone who has tried to determine the percentage of opioids in Cabell County that were taken for something other than a legitimate medical purpose. *See* 5/6 Tr. (Priddy), at 226:23–227:2.

21. To the extent an individual overdoses on a prescription opioid, Cabell County EMS does not attempt to determine the pharmacy that dispensed that prescription or the distributor that serves that pharmacy. *See* 5/6 Tr. (Priddy), at 227:3–9.

22. To the extent an individual overdoses on an illicit opioid, Cabell County EMS does not attempt to determine whether that individual ever had a valid prescription for an opioid medication. *See* 5/6 Tr. (Priddy), at 227:10–14.

23. All Cabell County EMS suspected overdoses are categorized the same way, regardless of what the suspected drug is, and Cabell County EMS does not record how many suspected overdose runs were due to opioids versus other substances. *See* 5/6 Tr. (Priddy) at 224:2–7, 224:14–18, 225:2–8.

V. Jan Rader

24. Jan Rader is the Huntington Fire Chief, and is also a nurse. *See* 5/7 Tr. (Rader) at 26:14–19, 27:16–19, 29:13–15.

25. Chief Rader has been with the Huntington Fire Department for 27 years. *See* 5/7 Tr. (Rader), at 27:24–28:1.

26. Chief Rader did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

27. Chief Rader did not offer any testimony concerning whether Defendants caused any harm to the Huntington or Cabell County resulting from legal or illegal opioids.

VI. Craig McCann

28. Craig McCann is a data analyst at Securities Litigation and Consulting Group, Inc. *See* 5/10 Tr. (McCann) at 9:1–8.

29. Dr. McCann was qualified as an expert on data processing, validating, reconciling, and summarizing large datasets as they relate to ARCOS and related governmental datasets. *See* 5/10 Tr. (McCann) at 20:3–7.

30. Dr. McCann did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

31. Dr. McCann did not offer any testimony concerning whether Defendants caused any harm to the Huntington or Cabell County resulting from legal or illegal opioids.

32. Dr. McCann is not an epidemiologist, a medical doctor or a pharmacist, nor is he an expert on the medical needs for prescription opioids. *See* 5/11 Tr. (McCann) at 65:19–66:2.

33. Dr. McCann has not studied the medical needs of Cabell/Huntington. *See* 5/11 Tr. (McCann) at 66:3–5.

34. Dr. McCann did not know how many prescription opioids should have been distributed to Cabell/Huntington. *See* 5/11 Tr. (McCann) at 66:6–9.

35. Dr. McCann did not perform any analysis to understand why the per capita distribution in Huntington and Cabell County was higher than the state and national averages. *See* 5/11 Tr. (McCann) at 130:11–18.

36. In assessing shipment data, Dr. McCann did not consider the relationship of prescription levels to distribution levels. *See* 5/11 Tr. (McCann) at 139:11–15.

37. Dr. McCann did not make any adjustments to his per capita distribution figures to account for overall prescription usage rates nationally, in West Virginia, or in Huntington/Cabell. *See* 5/11 Tr. (McCann) at 175:3–6.

38. Dr. McCann could say whether or not all of the shipment charts he showed to the Court during his direct examination show over-supply or under-supply of prescription opioids. *See* 5/11 Tr. (McCann) at 66:10–13.

39. Dr. McCann was not aware of any evidence that Defendants distributed to pharmacies that were not licensed by DEA or that were not licensed by the West Virginia Board of Pharmacy. *See* 5/11 Tr. (McCann) at 69:12–16, 182:21–183:7; *see also* 5/12 Tr. (McCann) at 65:14–18.

40. Dr. McCann was not aware of any shipments that were shipped to a pharmacy without an order placed by the pharmacy for that shipment. *See* 5/12 Tr. (McCann) at 65:19–23.

41. Dr. McCann was not aware of any pills that any distributor shipped that was dispensed without a valid prescription. *See* 5/11 Tr. (McCann) at 183:8–11.

42. Dr. McCann was not aware of any evidence that the distribution of prescription opioids reflected in the ARCOS data exceeded prescriptions written by doctors. *See* 5/11 Tr. (McCann) at 183:12–15.

43. Dr. McCann did not identify any of Defendants' pharmacy customers as pill mills. *See* 5/11 Tr. (McCann) at 183:16–20.

44. Plaintiffs' counsel selected the specific pharmacies that Dr. McCann included in his summary charts. 5/12 Tr. (McCann) at 13:14–25, 56:20–25.

45. The specific pharmacies included in Dr. McCann's summary charts were not selected as average pharmacies. *See* 5/12 Tr. (McCann) at 18:16–20.

46. Dr. McCann used the wrong dataset to perform his suspicious order "flagging" methodologies, and therefore the results of those methodologies are not reliable and cannot be credited.

a. To perform his suspicious order "flagging" methodologies, Dr. McCann uses shipment data from DEA's ARCOS database as supplemented by distributors' transactional data. *See* 7/8 Tr. (Boberg) at 161:13–21, 162:15–20.

b. Dr. McCann's dataset includes only shipment data, not data on all orders received by distributors. *See* 7/8 Tr. (Boberg) at 162:15–20.

c. By using shipment data, Dr. McCann ignores orders that were placed but not shipped, which can include blocked orders for regulatory reasons, as well as orders for out-of-stock products, or orders that aren't shipped due to other issues, such as a customer's financial or credit issues. *See* 7/8 Tr. (Boberg) at 162:21–163:9.

d. The orders that McKesson and other distributors blocked under their suspicious order monitoring programs are not included in Dr. McCann's dataset. *See* 7/8 Tr. (Boberg) at 164:5–17.

e. By using shipment data instead of all order data, Dr. McCann skews the results of his algorithms, because the orders that are not in the data are likely to be the ones that the algorithm is trying to flag—such as the largest orders that were blocked for size—and exclusion of those orders changes the flagging results for the remaining orders when trying to identify, for example, things like what is an "unusual size" order. *See* 7/8 Tr. (Boberg) at 164:18–165:15.

47. Dr. McCann has testified as an expert witness for the plaintiffs in multiple opioid litigations, and in total has been compensated roughly $5 to $6 million. *See* 5/11 Tr. (McCann) at 183:24–184:14.

VII. Joseph Werthammer

48. Joseph Werthammer is a pediatrician with a subspecialty in neonatology, and currently works as a full-time neonatologist. *See* 5/21 Tr. (Werthammer), at 9:10–17, 10:5–7.

49. Dr. Werthammer practices at the Cabell-Huntington Hospital and the School of Medicine at Marshall University. *See* 5/21 Tr. (Werthammer), at 10:2–4.

50. Dr. Werthammer did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

51. Dr. Werthammer did not offer any testimony concerning whether Defendants caused any harm to the Huntington or Cabell County resulting from legal or illegal opioids.

VIII. Scott Lemley

52. Scott Lemley is the Director of Innovation for the City of Huntington. 5/21 Tr. (Lemley) at 112:4–13. He previously worked as a Criminal Intelligence Analyst for the Huntington Police Department and as a member of the Mayor's Office of Drug Control Policy from 2010–2017. *See id.* at 112:22–113:6.

53. Mr. Lemley did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

54. Mr. Lemley did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

55. Mr. Lemley compiles statistical data on drug overdose deaths, but there is no way to know from Mr. Lemley's statistics whether an opioid present in someone's system was the cause of death if there were other drugs present. *See* 5/21 Tr. (Lemley) at 231:19–23.

56. There is no way to know from Mr. Lemley's statistics whether a person who overdosed was ever prescribed opioids. *See* 5/21 Tr. (Lemley) at 231:24–232:2.

57. There is no way to know from Mr. Lemley's statistics whether an overdose victims ever used a medication distributed by any of the Defendants. *See* 5/21 Tr. (Lemley) at 232:3–11.

58. Mr. Lemley never calculated statistics relating to the Defendants. *See* 5/21 Tr. (Lemley) at 200:23–201:1.

59. The Mayor's Office of Drug Control Policy ("MODCP") was instituted in late 2014 "to help deal with the addiction issues that we had going on in Huntington to find innovative and creative ideas on how to address these, to determine the scope of the problem." 5/21 Tr. (Lemley) at 136:11–23. The MODCP was discontinued in 2017. *See id.* at 143:20–22, 195:24–196:1.

60. Mr. Lemley was responsible for compiling the Mayor's Office of Drug Control Policy's 2015 strategic plan, 5/21 Tr. (Lemley) at 164:15–24, and reviewed the Mayor's Office of Drug Control Policy's 2017 strategic plan "to ensure it was factually accurate." 5/21 Tr. (Lemley) at 164:15–24

61. The MODCP's 2015 strategic plan did not make any recommendations concerning the amount of opioids a wholesaler could ship, did not make any recommendation to require any new reporting by wholesale distributors, and did not propose to make any change in state law that related in any way whatsoever to wholesale drug distributors. 5/21 Tr. (Lemley) at 210:11–14, 210:23–25, 211:1–4. In fact, the MODCP's 2015 strategic plan did not mention wholesale distributors at all. *See id.* at 211:17–21.

62. The MODCP's 2017 strategic plan did not make any recommendations concerning the amount of opioids a wholesaler could ship, did not make any recommendation to require any new reporting by wholesale distributors, and did not make any recommendation of new licensure requirements for wholesale distributors. 5/21 Tr. (Lemley) at 218:2–5, 218:15–20. In fact, the MODCP's 2017 strategic plan did not mention wholesale distributors at all. *See id.* at 218:21–25.

IX. James Rafalski

63. James Rafalski previously was employed as a DEA Diversion Investigator from 2004 to 2017. *See* 5/26 Tr. (Rafalski) at 15:21–16:9, 124:3–6.

64. Plaintiffs tendered Mr. Rafalski as an expert witness, but the Court reserved judgment on whether Mr. Rafalski was qualified. *See* 5/26 Tr. (Rafalski) at 32:20–23, 33:9–15, 43:12-2 .

65. Mr. Rafalski did not employ a reliable methodology and his criticisms of Defendants were not credible. *See supra* Findings ¶¶ 153–165.

66. Mr. Rafalski evaluated only the three distributors who are defendants in this case. *See* 5/26 Tr. (Rafalski) at 116:4-6. He did not evaluate any of the other participants in the closed system of distribution in Cabell/Huntington, including manufacturers, other distributors, or pharmacies. *See id.* at 116:7–12.

67. Mr. Rafalski did not offer any testimony or opinions concerning Defendants' conduct in Cabell/Huntington.

68. Mr. Rafalski has not performed any calculation to estimate actual diversion of prescription opioids. *See* 5/26 Tr. (Rafalski) at 250:10–17.

69. Mr. Rafalski did not know how many orders meeting the regulatory definition of a suspicious order have been diverted over time. *See* 5/26 Tr. (Rafalski) at 205:18–22.

70. Mr. Rafalski was unaware of DEA ever telling any distributor that the level of distribution into Huntington/Cabell was excessive or improper. *See* 5/26 Tr. (Rafalski) at 179:4–8.

71. Mr. Rafalski did not evaluate whether the pharmacies in Cabell/Huntington were complying with their legal obligations. *See* 5/26 Tr. (Rafalski) at 134:20–25.

72. Mr. Rafalski did not review pharmacy records, how the records were maintained, or whether pharmacies dispensed opioids in accordance with their corresponding responsibility. *See* 5/26 Tr. (Rafalski) at 135:1–7.

73. Mr. Rafalski did not offer any opinions about whether diversion occurred at a pharmacy level. *See* 5/26 Tr. (Rafalski) at 135:8–13. Nor did he identify any diversion at the pharmacy level. *Id.*

74. Mr. Rafalski could not identify any pills shipped by Defendants that went to a pill mill doctor or to fill an improper prescription. *See* 5/26 Tr. (Rafalski) at 130:9–131:2.

75. Mr. Rafalski's flagging analysis is based on an erroneous assumption that no due diligence was performed on orders exceeding a threshold. *See* 5/26 Tr. (Rafalski) at 101:22–102:3.

76. Mr. Rafalski does not know how many cancer patients, patients recovering from surgery, or patients receiving end of life care would be deprived of medications if the orders he asserted should have been blocked were not shipped by Defendants. *See* 5/26 Tr. (Rafalski) at 217:2–7, 218:1–20.

X. Chuck Zerkle

77. Charles "Chuck" Zerkle currently serves as Cabell County Sheriff, and was first elected to that position in 2016. 5/27 Tr. (Zerkle) at 84:12–16, 85:4–8.

78. Sheriff Zerkle did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

79. Sheriff Zerkle did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

XI. Lyn O'Connell

80. Lyn O'Connell works for the Joan C. Edwards School of Medicine as the Associate Director of Addiction Sciences. *See* 5/27 Tr. (O'Connell) at 192:14-16.

81. Dr. O'Connell did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

82. Dr. O'Connell did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

83. Dr. O'Connell did not testify as to specific treatment capacity numbers and did not quantify any needs for funding for any opioid-related programs.

XII. Joseph Rannazzisi

84. Joseph Rannazzisi worked at DEA from March 1986 to October 2015. *See* 6/7 Tr. (Rannazzisi) at 165:2–3. He was head of DEA's Office of Diversion Control for ten years, from July 2005 to October 2015. *See id.* at 165:7–8; *see also* 6/8 Tr. (Rannazzisi) at 211:23–213:2.

85. In his role at DEA, Mr. Rannazzisi oversaw all major pharmaceutical investigations performed by DEA, clandestine lab operations, promulgating regulations, and the aggregate production quota. *See* 6/7 Tr. (Rannazzisi) at 172:22–173:10.

86. Mr. Rannazzisi had no interactions with distributors of controlled substances before 2006 and no knowledge of DEA's interactions with distributors before 2006. *See* 6/9 Tr. (Rannazzisi) at 14:19–15:6.

87. Since 2017, Mr. Rannazzisi has made about $860,000 testifying as an expert witness on behalf of the plaintiffs in opioid litigation. *See* 6/8 Tr. (Rannazzisi) at 208:3–8.

88. Mr. Rannazzisi had no knowledge of any distributions into Cabell/Huntington. *See* 6/10 Tr. (Rannazzisi) at 23:5–9.

89. Mr. Rannazzisi could not identify any orders that were shipped into Cabell/Huntington that DEA believed should have been blocked by one of the Defendants but were not. *See* 6/9 Tr. (Rannazzisi) at 14:6–17.

90. Mr. Rannazzisi admitted that he could not identify any occasion "where [he] or someone at DEA told one of the distributors in this case that they should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy." *See* 6/9 Tr. (Rannazzisi) at 99:10–16.

91. Mr. Rannazzisi admitted that he could not identify any instance where any Defendant "supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA." *See* 6/9 Tr. (Rannazzisi) at 151:19–23.

92. Mr. Rannazzisi admitted that he could not identify any instance where any Defendant "supplied prescription opioids to a DEA licensed pharmacy in Huntington or Cabell that the DEA had warned the distributor not to supply." *See* 6/9 Tr. (Rannazzisi) at 151:24–152:3.

93. While in government, Mr. Rannazzisi testified approximately 50-70 times that medicine cabinet diversion was the primary source of diversion of prescription opioids in the United States. *See* 6/10 (Rannazzisi) at 88:13–89:21. He confirmed that this was the official view of DEA. *See id.* at 89:11–14. On re-direct examination, he testified he did not believe what he had repeatedly testified to under oath. *See id.* at 89:15-21.

XIII. Gordon Smith

94. Gordon Smith is a public health epidemiologist at the West Virginia University School of Public Health. *See* 6/10 Tr. (Smith) at 97:21–25.

95. Dr. Smith was qualified as an expert on the subject of epidemiology, drug overdoses, and overdose data and trends for the State of West Virginia and Cabell County. *See* 6/10 Tr. (Smith) at 114:11–14.

96. Dr. Smith did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

97. Dr. Smith did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

98. Dr. Smith did not offer any opinions about the number of prescription opioid overdoses for the period prior to 2001. *See* 6/10 Tr. (Smith) at 157:15–18.

99. Dr. Smith's analysis did not consider the source (illicit versus prescription) of any opioid found in overdose data; he simply identified the molecule(s) present at the time of death. *See* 6/10 Tr. (Smith) at 134:15–135:2.

100. Dr. Smith could not distinguish between drugs sourced from a trafficking organization versus sourced from a pharmacy. *See* 6/10 Tr. (Smith) 155:15–156:1.

101. Dr. Smith did not offer any opinion that drugs involved in overdose deaths originated from any defendant in this case. *See* 6/10 Tr. (Smith) at 156:2–7.

102. Dr. Smith did not consider whether an individual decedent may have used prescription opioids as prescribed versus using them in a non-prescribed manner. *See* 6/10 Tr. (Smith) at 163:7–15.

103. Dr. Smith did not try to evaluate how many overdose deaths were associated with prescription opioids that had been prescribed legitimately versus obtained by illicit means. *See* 6/10 Tr. (Smith) at 163:16–164:8.

104. Dr. Smith testified that there is no way to distinguish between prescription and illicit fentanyl based on toxicology reports alone, but Dr. Smith did not consider additional sources. *See* 6/10 Tr. (Smith) at 178:22–179:10.

105. Dr. Smith had no reason to dispute the statement, in a study he relied on, that the "majority of persons using prescription pain relievers for non-medial indications report receiving their drugs for free from a friend or relative." *See* 6/10 Tr. (Smith) at 185:7–24.

106. Dr. Smith's data undercounts heroin and illicit fentanyl deaths.

a. Heroin deaths may be misattributed in death certificate data to (prescription) morphine deaths because heroin metabolizes into morphine. *See* 6/10 Tr. (Smith) at 165:6–166:16.

b. Dr. Smith did not know how many heroin deaths were misattributed to morphine deaths. *See* 6/10 Tr. (Smith) at 166:21–167:7.

c. Dr. Smith confirmed that an example death certificate shown to him for a Cabell County decedent was counted as a morphine (prescription) death, despite findings from the medical examiner indicating heroin use. *See* 6/10 Tr. (Smith) at 173:1–177:7.

107. Despite acknowledging that heroin deaths can be undercounted based only on toxicology reports, Dr. Smith did not look at any individual death certificates or law enforcement records to reach his conclusion that the presence of heroin prior to 2011 was small. *See* 6/10 Tr. (Smith) at 177:9–17.

108. Dr. Smith was unaware of DEA reports indicating that illicit fentanyl was present in the United States as early as 2005 when forming his opinion that any illicit fentanyl

deaths prior to 2014 should be attributed to prescription fentanyl. *See* 6/10 Tr. (Smith) at 140:19–141:8, 179:11–17, 179:24–180:25, 181:25–182:3.

109. Dr. Smith did not know if the rate of prescription use in decedents is the same, higher, or lower than the rate of prescription drug use in the general public. *See* 6/10 Tr. (Smith) at 186:19–24.

110. Dr. Smith was aware that academic literature has linked a reduction in the amount of prescription opioids available, due to a decline in prescribing by physicians with an increase in the use of heroin. *See* 6/10 Tr. (Smith) at 212:16–21, 213:9–15.

XIV. Jakki Mohr

111. Jakki Mohr is a Professor of Marketing at the University of Montana. *See* 6/10 Tr. (Mohr) at 227:24–228:2.

112. Dr. Mohr was qualified as an expert in the field of marketing. *See* 6/10 Tr. (Mohr) at 234:23–24.

113. Dr. Mohr did not offer any testimony concerning Defendants' conduct in Cabell/Huntington. *See* 6/11 Tr. (Mohr) at 98:21–25.

114. Dr. Mohr did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids. *See* 6/11 Tr. (Mohr) at 97:23–98:3.

115. Dr. Mohr offered no opinion that any marketing materials or marketing communications by any of Defendants were false or misleading. *See* 6/11 Tr. (Mohr) at 96:11–15, 97:3–5, 123:22–124:2.

116. Dr. Mohr offered no opinion that any of Defendants' marketing activities was unlawful or improper. *See* 6/11 Tr. (Mohr) at 112:19–21, 124:3–10.

117. Dr. Mohr testified that the marketing activities engaged in by the Defendants are typical across many industries. *See* 6/11 Tr. (Mohr) at 112:22–113:3, 127:3–23.

118. Dr. Mohr did not evaluate the effect of Defendants' marketing activities on sales of prescription opioids. *See* 6/11 Tr. (Mohr) at 97:6–13.

119. Dr. Mohr did not evaluate the effect of Defendants' marketing activities on any pharmacy in Huntington or Cabell. *See* 6/11 Tr. (Mohr) at 97:22–98:3.

120. Dr. Mohr did not identify any instance where a Defendant advertised a manufacturer's opioid product to a retail pharmacy in Huntington or Cabell. *See* 6/11 Tr. (Mohr) at 98:21–25.

121. Dr. Mohr offered no opinion on the impact of any continuing medical education program on prescription opioid sales. *See* 6/11 Tr. (Mohr) at 139:17–25.

122. The marketing activities of Defendants that Dr. Mohr reviewed were directed to pharmacies, not patients or doctors. *See* 6/11 Tr. (Mohr) at 94:14–95:2.

XV. Katherine Keyes

123. Katherine Keyes is an Associate Professor of Epidemiology at Columbia University's Mailman School of Public Health. *See* 6/11 Tr. (Keyes) at 150:20–151:3.

124. Dr. Keyes was qualified as an expert in the field of epidemiology, specializing in opioid use, Opioid Use Disorder, and related harms. *See* 6/11 Tr. (Keyes) at 160:16–18.

125. Dr. Keyes did not evaluate any specific distributors. *See* 6/14 Tr. (Keyes) at 21:19–23.

126. Dr. Keyes's expert report does not mention McKesson, Cardinal Health, or AmerisourceBergen. *See* 6/14 Tr. (Keyes) at 21:24–22:1.

127. Dr. Keyes had no knowledge of the operations of McKesson, Cardinal Health, or AmerisourceBergen specifically in Cabell and Huntington. *See* 6/14 Tr. (Keyes) at 25:17–23.

128. Dr. Keyes did not undertake any analysis of the pain needs in Cabell/Huntington. *See* 6/14 Tr. (Keyes) at 20:8–10.

129. Dr. Keyes did not evaluate how many prescription opioid pills are needed to meet the medical needs in Cabell/Huntington. *See* 6/14 Tr. (Keyes) at 18:22–19:19.

130. Dr. Keyes did not assess any individual distributor's contribution to opioid supply relative to other distributors. *See* 6/14 Tr. (Keyes) at 23:22–25.

131. Dr. Keyes did not evaluate how many opioids McKesson, Cardinal Health, or AmerisourceBergen shipped into Huntington and Cabell County. *See* 6/14 Tr. (Keyes) at 24:1–9.

132. Dr. Keyes did not offer any opinion as to how many opioids McKesson, Cardinal Health, or AmerisourceBergen shipped to any specific pharmacy in Huntington or Cabell County. *See* 6/14 Tr. (Keyes) at 26:7–10.

133. Dr. Keyes was unaware of any occasion where McKesson, Cardinal Health, or AmerisourceBergen shipped opioids in excess of the quotas set by DEA. *See* 6/14 Tr. (Keyes) at 26:18–22.

134. Dr. Keyes was unaware of any occasion where McKesson, Cardinal Health, or AmerisourceBergen shipped opioids into Huntington or Cabell County in excess of the levels prescribed by doctors. *See* 6/14 Tr. (Keyes) at 27:4–7.

135. Dr. Keyes did not review the content of any distributor's Suspicious Order Monitoring Program. *See* 6/14 Tr. (Keyes) at 25:24–26:2.

136. Dr. Keyes did not review any specific orders for prescription opioids made by pharmacies in Huntington or Cabell County. *See* 6/14 Tr. (Keyes) at 26:3–6.

137. Dr. Keyes could not identify a single prescription opioid distributed by the Defendants in Cabell County or Huntington that should have been investigated and not shipped. *See* 6/14 Tr. (Keyes) at 26:11–17.

138. Dr. Keyes did not identify any shipments by distributors that were diverted before they were delivered to pharmacies. *See* 6/14 Tr. (Keyes) at 68:6–10, 69:18–23.

139. In her testimony, Dr. Keyes relied on a definition of "cause" under which a cause need not be temporally proximate to the outcome, *see* 6/14 Tr. (Keyes) at 207:7–10, a cause can be followed by many intervening causes, *id.* at 207:11–14, 207:23–25, a cause can be distant in time, *id.* at 207:18–22, a cause does not need to be the closest or most recent cause to be considered a cause, *id.* at 208:1–4, and something does not need to be the direct cause to be considered a cause, *id.* at 208:14–17.

XVI. Lacey Keller

140. Lacey Keller is co-owner of MK Analytics, a data and analytics company. *See* 6/15 Tr. (Keller) at 51:24–52:5.

141. Ms. Keller was qualified as an expert in the field of data analytics. *See* 6/15 Tr. (Keller) at 58:19–23.

142. Ms. Keller did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

143. Ms. Keller did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

144. Ms. Keller offered testimony on "top 1% prescribers" in Cabell/Huntington, but she had no opinion on whether prescriptions written by those prescribers were medically unnecessary or medically improper. *See* 6/15 Tr. (Keller) at 165:16–22. She had no opinion that any prescription written by any of those prescribers should not have been filled by a pharmacy. *See id.* at 166:21–167:13. And she had no opinion that any of those prescribers were prescribing too many opioids, not enough opioids, or just enough opioids. *See id.* at 169:9–15.

145. Ms. Keller had no opinion as to what Defendants should have done with knowledge that their customers were filling prescriptions from any "top 1% prescribers" in Cabell/Huntington, *see* 6/15 Tr. (Keller) at 191:3–15, nor did she offer any opinion that a Defendant should have taken any action against a pharmacy that was filling prescriptions for such top prescribers, *see id.* at 251:6–13.

146. Ms. Keller had no evidence that Defendants had direct connections with any of the "top 1% prescribers" she identified in Cabell/Huntington. *See* 6/15 Tr. (Keller) at 249:12–15.

147. Ms. Keller testified that complaints and investigations against doctors in West Virginia are confidential until a final resolution, *see* 6/15 Tr. (Keller) at 237:1–12, 260:18–25, and can take years to complete, *see id.* at 265:15–25. Ms. Keller identified no way that Defendants would have been able to learn about any such complaints or investigations before a final resolution.

XVII. Nancy Young

148. Nancy Young is the Executive Director of Children and Family Futures, a non-profit organization based in California that works on public policy issues affecting children of parents with Substance Use Disorders. *See* 6/16 Tr. (Young) at 9:2–13.

149. Dr. Young was qualified as an expert on the impact of opioids on children and families and remedies to address their impact. *See* 6/16 Tr. (Young) at 18:5–7.

150. Dr. Young did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

151. Dr. Young did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

152. Dr. Young did not visit Cabell in developing her report; instead, she developed her report based on literature. 6/16 Tr. (Young) at 30:2–4, 30:19–22.

153. Dr. Young offered opinions on programs for children and families with opioid use disorders, costs for certain programs, and the population that she believed require interventions. *See* 6/16 Tr. (Young) at 17:9–14, 26:16–19.

154. Dr. Young's recommendations apply to children with parents who are using substances other than opioids. *See* 6/16 Tr. (Young) at 68:11–14.

155. Dr. Young is not an expert in healthcare economics, *see* 6/16 Tr. (Young) at 119:19–20, and offered no opinion on who should pay for or provide the programs she discussed.

156. Dr. Young offered no opinion as to the needs in the community in Huntington and Cabell County. *See* 6/16 Tr. (Young) at 129:10–13.

157. Dr. Young did not evaluate the capacity of existing programs in Cabell and Huntington. *See* 6/16 Tr. (Young) at 83:2–6, 89:2–6. Accordingly, Dr. Young provided no opinion as to the capacity of the programs operating in Huntington and Cabell County, including whether they are at capacity or have available capacity, *see id.* at 129:14–21, or whether sufficient services are available, *see id.* at 82:13–17, 83:16–18. Dr. Young testified that she "believe[d] there are other experts that are doing that." *See id.* at 83:16–19.

158. Dr. Young was not asked to, and did not, assess or evaluate the existing programs in Cabell County or make a determination of whether the existing programs are effective. *See* 6/16 Tr. (Young) at 30:16–19, 68:19–69:2, 120:8–19.

159. Dr. Young did not know, and did not look at, whether any of the existing programs in Cabell currently have a funding deficit. *See* 6/16 Tr. (Young) at 90:21–91:1.

160. Dr. Young did not consider cost data from West Virginia when she developed her cost recommendations, even when comparable programs already existed in West Virginia. *See* 6/16 Tr. (Young) at 86:2–19, 90:5–8. Dr. Young testified that she understood that local cost data would be provided by "other experts." *See id.* at 121:14–22.

161. Dr. Young did not evaluate whether any of the programs she considered are run or funded by Cabell County or the City of Huntington. *See* 6/16 Tr. (Young) at 122:6–14, 122:17–123:7.

162. Dr. Young estimated five populations that feed into Dr. Alexander's redress model. *See* 6/16 Tr. (Young) at 104:6–10, 104:17–105:7. None of those populations were based on data specific to Huntington and Cabell County. *See id.* at 106:21–24, 107:5–13, 110:9–18, 111:10–17, 113:3–8, 113:16–18, 114:11–14. None of them are limited to women who took prescription opioids. *See id.* at 118:2–6. None of Dr. Young's population estimates are current, and she did not forecast the populations in the future. *See id.* at 119:2–11.

163. Dr. Young's population data does not distinguish between opioids and other substances. *See* 6/16 Tr. (Young) at 31:5–11.

XVIII. Kevin Yingling

164. Kevin Yingling is currently Chairman of the Board for the Cabell County Health Department and the Chairman of the Board of Tri-State Medical Missions. *See* 6/16 Tr. (Yingling) at 134:6–9. Dr. Yingling also works at PROACT once a week providing medication assisted treatment. *See id.* at 152:2–8.

165. Dr. Yingling is a practicing internal medicine doctor and a pharmacist who has both worked at pharmacies and has taught pharmacy students. 6/16 Tr. (Yingling) at 152:11-19, 172:8–17.

166. Dr. Yingling did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

167. Dr. Yingling did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

168. Dr. Yingling is unable to identify any opioid-related programs administered by the Cabell-Huntington Health Department that receive funding from Huntington or Cabell. *See* 6/16 Tr. (Yingling) at 193:16-194:4.

169. Dr. Yingling did not have specific knowledge of any prescription opioid pills that entered the Huntington or Cabell communities without a prescription from a doctor. *See* 6/16 Tr. (Yingling) at 172:2-7.

170. Dr. Yingling is not aware of any shipments from distributors to anyone in Cabell County other than DEA registered, state licensed pharmacies or hospitals. *See* 6/16 Tr. (Yingling) at 173:21-25.

XIX. Thomas McGuire

171. Thomas McGuire is a health economist in the Department of Healthcare Policy at Harvard Medical School. *See* 6/17 Tr. (McGuire) at 7:21-8:3.

172. Dr. McGuire was qualified as an expert in the field of health economics. *See* 6/17 Tr. (McGuire) at 12:13-15.

173. Dr. McGuire did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

174. Dr. McGuire did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

175. Dr. McGuire's analysis was backward-looking. *See* 6/17 Tr. (McGuire) at 41:8-13. He offered no opinion on how much it would cost to fund a remediation plan to address addiction or other opioid-related harms in Cabell/Huntington. *See id.* at 41:22-42:1.

176. Dr. McGuire's analysis of economic costs associated with the distribution of prescription opioids in Cabell/Huntington included all distributions by all distributors; it did not:

a. Calculate the costs attributable just to distributions by Defendants, *see* 6/17 Tr. (McGuire) at 45:16–24, 46:14–47:1;

b. Calculate the costs attributable just to wrongful distributions by Defendants, *see* 6/17 Tr. (McGuire) at 48:10–16;

c. Calculate the costs attributable just to distributions in excess of good-faith prescriptions, *see* 6/17 Tr. (McGuire) at 48:21–49:1;

d. Calculate the costs attributable just to harms caused by prescription opioids (not illicit opioids, *see* 6/17 Tr. (McGuire) at 48:10-16.

177. Dr. McGuire did not attempt to calculate harms caused by the sale and distribution of prescription opioids by illegal actors, such as drug cartels and traffickers. *See* 6/17 Tr. (McGuire) at 49:7–18.

178. Dr. McGuire acknowledged that he cannot second-guess the risk benefit calculation that prescribers make when they prescribe opioids for the medical treatment of their patients. *See* 6/17 Tr. (McGuire) at 36:1-7.

179. Dr. McGuire's analysis did not consider the benefits of pain reduction or quality of life associated with reduced pain, unless those led to increased workforce participation. *See* 6/17 Tr. (McGuire) at 48:21–49:1, 54:4–9.

180. Dr. McGuire did not allocate to the good faith prescribing decisions of doctors any of the economic costs he identified with respect to the distribution of opioids in Cabell/Huntington. *See* 6/17 Tr. (McGuire) at 54:13-18.

XX. Judith Feinberg

181. Judith Feinberg is employed at the West Virginia University School of Medicine as a Professor of Behavioral Medicine and Psychiatry, Professor of Medicine in the section of infectious diseases, and Doctor E.B. Flink Vice Chair of Medicine for Research. *See* 6/17 Tr. (Feinberg) at 88:23-89:10.

182. Dr. Feinberg was qualified as an expert in the prevention and treatment of infectious diseases associated with opioid use disorder and injection opioid drug use. *See* 6/17 Tr. (Feinberg) at 106:14-17.

183. Dr. Feinberg offered no opinions about any of the distributors. *See* 6/17 Tr. (Feinberg) at 161:24–162:2.

184. Dr. Feinberg did not offer any opinions about how any drug was distributed. *See* 6/17 Tr. (Feinberg) at 162:3–8.

185. Dr. Feinberg did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

186. Dr. Feinberg did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

187. Dr. Feinberg's opinions were limited to the infectious consequences of injection drug use. *See* 6/17 Tr. (Feinberg) at 160:23–161:1.

188. The risk of infectious diseases that Dr. Feinberg discusses is a risk that arises as a consequence of the means of drug delivery—namely, the injection of drugs through the skin. *See* 6/17 Tr. (Feinberg) at 161:8–13.

189. Injection drug use relates only to use of illicit drugs, or non-medical use of licit drugs. *See* 6/17 Tr. (Feinberg) at 162:20–163:2, 164:19–165:2, 166:18–21.

190. None of Dr. Feinberg's opinions related to the medical use of prescription opioids. *See* 6/17 Tr. (Feinberg) at 166:22–167:1.

191. Dr. Feinberg does not offer any opinion about infectious disease risks associated with the oral administration of opioids. *Cf.* 6/17 Tr. (Feinberg) at 161:8–13 (opinions relate to risks associated with injection drug use only); *id*. at 115:2–9 (same).

XXI. William "Skip" Holbrook

192. Skip Holbrook was Chief of the Huntington Police Department from 2007–2014, *see* 6/17 Tr. (Holbrook) at 189:19-190:3, and he served on the Appalachia HIDTA Executive Board, *see id.* at 190:4-7.

193. Chief Holbrook did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

194. Chief Holbrook did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

XXII. Caleb Alexander

195. Caleb Alexander is the owner and co-founder of a consultancy called Monument Analytics, a Professor of Epidemiology and Medicine at Johns Hopkins University, and a general internist. *See* 6/28 Tr. (Alexander) at 8:9–10, 9:11–14, 9:22–25.

196. Dr. Alexander was qualified as an expert in the field of epidemiology and opioid abatement intervention. *See* 6/28 Tr. (Alexander) at 18:25–19:2.

197. Dr. Alexander offered no opinions on the conduct of any of the three distributors. *See* 6/28 Tr. (Alexander) at 121:17–20.

198. Dr. Alexander did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids. *See* 6/28 Tr. (Alexander) at 23:24–24:4.

199. Dr. Alexander offered no opinion on funding sources, including whether Cabell or Huntington have funded any of the recommended programs in the past. *See* 6/28 Tr. (Alexander) at 125:6–12, 125:16–20.

200. Dr. Alexander offered no opinion on whether Cabell County or Huntington would need to pay for any aspect of his plan if it was put into place, or who should pay for it more generally. *See* 6/28 Tr. (Alexander) at 126:5–9, 126:21–23.

201. Dr. Alexander offered no opinions on the capacity or incremental need of the opioid-related programs already in place in Cabell/Huntington. *See* 6/28 Tr. (Alexander) at 55:19-57:10, 106:5-107:24. He did not "subtract out the level of services that are currently being provided in the City of Huntington and Cabell County," *see id.* at 96:18-21, nor did he estimate "what would be needed to fill out the gaps or patch up where there are current holes" from existing programs, *see id.* at 97:5-7.

202. Dr. Alexander did not do any analysis of "costs or losses incurred by Cabell County or the City of Huntington in the past" due to the opioid crisis or providing programs in response to the opioid crisis. *See* 6/28 Tr. (Alexander) at 97:12–17.

203. Dr. Alexander testified that he had a "conversation or two" with Mr. Barrett about developing the total costs of the plan. *See* 6/28 Tr. (Alexander) at 145:13-18. However, Mr. Barrett testified that he spoke with Dr. Alexander on a "weekly basis up through August," and continued to speak with him after August. *See* 6/29 Tr. (Barrett) at 76:20–25, 77:1–9.

204. Dr. Alexander has submitted expert reports with his abatement model in three other opioid cases: Ohio, Rhode Island, and Washington. *See* 6/28 Tr. (Alexander) at 181:3–14, 184:6–8, 187:21–23. In those reports, he relied on a proprietary model (called the "Apollo model") for purposes of his abatement model. *See id.* at 182:1–14, 185:4–17, 188:7–10. The Apollo model is complex and involves many variables and inputs. *See id.* at 183:13-18. Dr. Alexander tested and calibrated the Apollo model extensively. *See id.* at 183:19–5. Dr. Alexander did not create or present an Apollo model for his report in Huntington and Cabell County. *See id.* at 192:25–193:2, 193:20–24.

205. In this litigation, Dr. Alexander did not rely on his own Apollo model but instead relied on a paper written by a consultant, Jack Homer. *See* 6/28 Tr. (Alexander) at 190:8-25. 191:2-20, 191:25-192:4, 197:25-198:2.

206. Dr. Alexander testified that he "consider[s] the background and training of authors" on which he relies. *See* 6/28 Tr. (Alexander) at 201:10-18. However, Dr. Alexander did not know Jack Homer, the paper's author, nor was he familiar with Homer's consulting company. *See id.* at 200:21-201:20.

207. Dr. Alexander testified that he "review[s]" and "consider[s]" the funding sources of papers he cites. *See* 6/28 Tr. (Alexander) at 202:8-15; *see also* 6/29 Tr. (Alexander) at 18:19-19:5. However, Dr. Alexander "wasn't aware" that the Homer paper was funded by two law firms that represent Plaintiffs in this litigation. *See* 6/28 Tr. (Alexander) at 201:21-202:12, 203:1-19, 203:24-205:6.

208. Dr. Alexander was also unaware that Jack Homer, on his website, states that the Homer paper was developed to "asses[] economic damages from the opioid epidemic" for "[t]wo plaintiff law firms involved in national litigation against opioid manufacturers and distributors." *See* 6/28 Tr. (Alexander) at 206:1-19.

209. Dr. Alexander provided no explanation for the decision to rely on the Homer paper in this litigation rather than his proprietary Apollo model.

XXIII. George Barrett

210. George Barrett is a forensic economist with the consulting firm of Brookshire Barrett & Associates. *See* 6/29 Tr. (Barrett) at 55:25–56:1, 56:9–11.

211. Mr. Barrett was qualified as an expert in in the field of forensic economics. *See* 6/29 Tr. (Barrett) at 66:6–7.

212. Mr. Barrett is "not qualified as an epidemiologist or as a social work expert to be able to provide specific input with regard to the items or the frequencies that an abatement program such as this would require." *See* 6/29 Tr. (Barrett) at 119:17–20.

213. Mr. Barrett is not a healthcare economist. *See* 6/29 Tr. (Barrett) at 145:23–24.

214. Mr. Barrett did not calculate the harm to Cabell/Huntington from the opioid epidemic. *See* 6/29 Tr. (Barrett) at 120:24–121:2.

215. Mr. Barrett did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

216. Mr. Barrett did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids, and testified that he had no opinion on causation. *See* 6/29 Tr. (Barrett) at 120:19-21.

217. Mr. Barrett did not determine how much of the total cost of Dr. Alexander's Abatement Plan is attributable to illicit opioids. *See* 6/29 Tr. (Barrett) at 120:14-16.

218. Mr. Barrett provided no opinion on how the Alexander plan should be administered. *See* 6/29 Tr. (Barrett) at 121:6-8.

219. Mr. Barrett has never calculated the cost of an Abatement Plan before. *See* 6/29 Tr. (Barrett) at 74:14-17.

220. The vast majority of cases in which Mr. Barrett has testified have been personal injury or wrongful death matters. *See* 6/29 Tr. (Barrett) at 144:2-5.

221. Mr. Barrett is not qualified to review the opinions of a medical expert or epidemiologist. 6/29 Tr. (Barrett) at 145:20-22.

222. Mr. Barrett has no opinion on who should pay for the different pieces of the plan. *See* 6/29 Tr. (Barrett) at 1698:25-169:4.

223. Mr. Barrett did no due diligence of the cost inputs provided by Dr. Alexander or Dr. Young. *See* 6/29 Tr. (Barrett) at 146:14-147:10.

224. Mr. Barrett did no due diligence of the population numbers provided by Dr. Alexander or Dr. Young. *See* 6/29 Tr. (Barrett) at 153:10-154:3.

225. If Dr. Alexander's or Dr. Young's inputs were wrong, Mr. Barrett's cost calculations are also wrong. *See* 6/29 Tr. (Barrett) at 156:4-10.

226. Mr. Barrett relied on costs inputs for Dr. Alexander for the syringe exchange program, which resulted in a yearly cost of $872,614 to serve 1,018 injection drug users. *See*

6/29 Tr. (Barrett) at 150:20-24; 151:2-7. Mr. Barrett did not consider alternate cost numbers, including testimony from Plaintiffs' witness Dr. Judith Feinberg that it cost her $60,000 a year to run a syringe exchange program that serves 1,400-1,500 people. *See id.* at 152:1-19.

227. Mr. Barrett could not say what percentage of the total cost of the Alexander plan is for people who develop OUD in the future. *See* 6/29 Tr. (Barrett) at 197:2–7.

228. Mr. Barrett did not evaluate whether any of the programs he costed out were already being provided in the community, *see* 6/29 Tr. (Barrett) at 157:4-8, and he did not adjust his calculations to take existing programs into account, *see id.* at 156:23–157:1, 157:9-14, 158:20-24, 160:4-12.

229. Mr. Barrett did not evaluate who pays for the current opioid-related programs that are already being conducted and run in Cabell-Huntington. *See* 6/29 Tr. (Barrett) at 169:5–10.

230. Mr. Barrett did not evaluate whether Huntington or Cabell County provide OUD treatment. *See* 6/29 Tr. (Barrett) at 161:7-9.

231. Mr. Barrett did not evaluate whether Huntington or Cabell County pay for OUD treatment, *see* 6/29 Tr. (Barrett) at 161:4-6, and he did not evaluate whether Huntington or Cabell County have ever paid for medical costs, *see id.* at 170:12-20, or would incur medical costs in the future, *see id.* at 170:21-25.

232. Mr. Barrett did not evaluate the current levels of spending by Huntington or Cabell County on opioid-related programs. *See* 6/29 Tr. (Barrett) at 120:1-3.

233. Mr. Barrett did not consider the funding projections of the Resiliency Plan in developing his analysis. *See* 6/29 Tr. (Barrett) at 167:10-14; 168:12-23.

XXIV. Steve Williams

234. Steve Williams is the current Mayor of the City of Huntington, and has served in that role since January 1, 2013. *See* 6/30 Tr. (Williams) at 7:23–8.

235. Mayor Williams did not offer any testimony concerning Defendants' conduct in Cabell/Huntington or anywhere else.

236. Mayor Williams did not offer any testimony concerning whether Defendants caused any harm to Huntington or Cabell County resulting from legal or illegal opioids.

237. Mayor Williams affirmed the judicial admissions regarding Manufacturers made in the Third Amended Complaint. *See* 6/30 Tr. (Williams) at 83:5–91:15.

238. Mayor Williams affirmed the judicial admissions regarding the Joint Commission made in Huntington's complaint against the Joint Commission. *See* 6/30 Tr. (Williams) at 97:2–102:12.

XXV. Chris Gilligan

239. Chris Gilligan is the Chief of the Division of Pain Medicine at Brigham & Women's Hospital in Boston, a teaching hospital for Harvard Medical School. *See* 7/2 Tr. (Gilligan) at 8:8–13; 12:23–13:9.

240. Dr. Gilligan was qualified as an expert in the field of pain management and the risks and benefits of prescription opioids. *See* 7/2 Tr. (Gilligan), at 26:9–11.

241. Dr. Gilligan testified regarding the role of the doctor and distributor, *see* 7/2 Tr. (Gilligan) at 9:6–13, 72:1–25, 73:4–17, 75:11–23, 146:22–147:3, 147:9–14, pain (and chronic pain) and its treatment, *id.* at 26:16–27:11, 32:22–33:6, 34:24–35:10 36:10–18, 37:9–38:5, the risk and benefits of opioids, *id.* at 38:6–12, 39:5–9, and the standard of care, *see, e.g.*, *id.* at 76:16–19.

XXVI. Tim Deer

242. Timothy Deer is a practicing physician with a specialty in anesthesiology and pain medicine. *See* 7/7 Tr. (Deer) at 8:6–9:23. Dr. Deer has practiced pain medicine in Charleston for 27 years, and runs the largest pain practice in West Virginia. *See id.* at 12:23–13:4, 22:6–15.

243. Dr. Deer was qualified as an expert in pain management and the standard of care for pain management. *See* 7/7 Tr. (Deer) at 37:8–10.

244. Dr. Deer testified regarding the standard of care for treating pain and prescribing opioids. *See, e.g.*, 7/7 Tr. (Deer) at 37:18–20, 39:24–40:5, 48:14–19. In particular, Dr. Deer testified that the standard of care for prescription opioids has changed over time, *see id.* at 129:3-8, and the changing standard of care has affected the rate at which doctors prescribed opioids in West Virginia, *see id.* at 129:9–13.

XXVII. James Hughes

245. James Hughes is an economist who specializes in microeconomics, particularly labor economics and health economics. *See* 7/7 Tr. (Hughes) at 209:24–25. Dr. Hughes is a Professor of Economics Emeritus at Bates College. *See id.* at 212:12–13.

246. Dr. Hughes was qualified as an expert in the fields of health economics and health insurance related to prescription medicines. *See* 7/7 Tr. (Hughes) at 220:18-25.

247. Dr. Hughes testified regarding the role of payors in the prescribing of opioids in West Virginia, *see* 7/7 Tr. (Hughes) at 211:2–3, health insurance coverage in West Virginia, *see, e.g.*, *id.* at 226:16–17, payors' considerations and incentives when reimbursing prescriptions, *id.* at 233:2-3, 232:12-24, 233:8-21, the tools available to payors to impact prescribing decisions, *see, e.g.*, *id.* at 243:22–244:2, 244:13–22, 245:4–11, 244:23–245:3, the data and analyses available to payors, *see, e.g.*, *id.* at 237:12–13, 238:1–6, 238:10–15, 239:2–4, 239:5–240:3, 240:4–9, and payors' coverage of

alternative treatments to prescription opioids, *id.* at 259:22–260:2, 260:14–21, 260:22–261:11.

XXVIII. Theodore Martens

248. Theodore Martens is a certified accountant and specializes in forensic accounting. *See* 7/8 Tr. (Martens) at 25:16-21; 27:17-21.

249. Mr. Martens was qualified as an expert in the fields of forensic accounting and data analytics. *See* 7/8 Tr. (Martens) at 40:20-22.

250. Mr. Martens testified about AmerisourceBergen's shipments of all prescription medications, including opioids, into Cabell County and Huntington. *See* 7/8 Tr. (Martens) at 47:23–48:4.

XXIX. Kevin Murphy

251. Kevin M. Murphy is the George J. Stigler Distinguished Service Professor of Economics in the Graduate School of Business in the Department of Economics at the University of Chicago. *See* 7/8 Tr. (Murphy) at 56:2-7.

252. Dr. Murphy was qualified as an expert in the field of economics and especially in health economics. *See* 7/8 Tr. (Murphy) at 63:19-21.

253. Dr. Murphy testified regarding distributors' role in the market for prescription opioids, *see* 7/8 Tr. (Murphy) at 64:20–69:9, the analytical limitations of observed associations, *id.* at 69:10–24, 70:19–7210, the lack of economic data in support of the theory that prescription opioid users transitioned to heroin and fentanyl use, *id.* at 72:11–103:8, and the infirmities with Dr. Keyes's estimation of the OUD population in Cabell/Huntington, *id.* at 106:21–117:6.

XXX. Peter Boberg

254. Peter Boberg is an economist at Charles River Associates, a Boston-based economic consulting firm. *See* 7/8 Tr. (Boberg) at 151:5–9, 156:2–11.

255. Dr. Boberg was qualified as an expert in the fields of econometrics, data analysis, and large datasets. 7/8 Tr. (Boberg) at 160:12–17.

256. Dr. Boberg's work involves applying economics and econometrics in the principles of data analysis to various settings. 7/8 Tr. (Boberg) at 155:21–156:1.

257. In his practice, Dr. Boberg commonly reviews models and analysis put forth by other experts. 7/8 Tr. (Boberg) at 157:7–10.

258. Dr. Boberg testified regarding the flaws in the flagging methodology presented by Mr. Rafalski (and prepared by Dr. McCann). *See supra* Findings ¶¶ 164–165; *see also, e.g.*, 7/8 Tr. (Boberg) at 161:13–21, 162:15–20.

259. Dr. Boberg also testified about McKesson's market share. *See infra* McKesson-Specific Findings ¶ 18; *see also, e.g.*, 7/8 Tr. (Boberg) at 186:9–16.

XXXI. John MacDonald, III

260. John MacDonald is the Principal Executive Officer and President of Berkley Research Group, a global consulting firm. 7/9 Tr. (MacDonald) at 8:23–9:6.

261. Mr. MacDonald was qualified as an expert in the fields of data analytics related to the pharmaceutical supply chain. 7/9 Tr. (MacDonald) at 16:11–13.

262. Mr. MacDonald's work involves analyzing large datasets to identify trends, including developing approaches to identify outlier events in healthcare data. 7/9 Tr. (MacDonald) at 10:24–11:14.

263. Mr. MacDonald testified regarding flaws in the flagging methodology presented by Mr. Rafalski (and prepared by Dr. McCann). *See* 7/9 Tr. (MacDonald) at 25:5–42:13

264. Mr. MacDonald also testified about Cardinal Health's distribution data including its non-opioid distributions, threshold-based suspicious order monitoring system, and due diligence. *See* 7/9 Tr. (MacDonald) at 14:4–13, 44:23–46:1, 50:6–18. 68:6–11.

XXXII. Robert Rufus

265. Robert Rufus is a certified public accountant and a forensic accountant. *See* 7/12 Tr. (Rufus) at 8:1–2, 9:21-24.

266. Dr. Rufus was qualified as an expert in public and forensic accounting. *See* 7/12 Tr. (Rufus) at 16:14–16.

267. Dr. Rufus testified regarding the City and County's prior involvement in opioid response programs, the City and County budget, and flaws in Mr. Barrett's and Dr. Alexander's data. *See, e.g.*, 7/12 Tr. (Rufus) at 20:19–24; 21:2–5; 21:15–17; 22:4–12; 22:13–19; 22:20–23:1; 23:2–5, 24:21–23; 25:1–7, 29:12–30:15; 31:15–17, 34:25–35:4.

XXXIII. Stephenie Colston

268. Stephenie Colston is currently the President and Chief Executive Office of Colston Consulting Group, which offers consulting services for non-governmental organizations and municipalities related to both mental health and substance use disorder services. *See* 7/12 Tr. (Colston) at 57:1–10.

269. Ms. Colston was qualified as an expert in the area of systems, programs, and services that provide care for people with substance use disorder, the structure, financing, and how to assess them, and trends in the substances that are being abused. *See* 7/12 Tr. (Colston) at 79:8–12.

270. Ms. Colston testified regarding the existence and availability of grant funding for substance abuse programs, *see, e.g.*, 7/12 Tr. (Colston) at 81:4–13, 82:7–9, Medicaid and Medicare reimbursement for OUD treatment, *id.* at 82:21–23, 119:10–12, and the methodological failures in Dr. Alexander's proposed Abatement Plan, *see, e.g.*, *id.* at 137:9–22.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

APPENDIX B: AMERISOURCEBERGEN DRUG CORPORATION ("ABDC")-SPECIFIC FINDINGS OF FACT AND CONCLUSIONS OF LAW

ABDC-SPECIFIC FINDINGS OF FACT

I. ABDC's Operations & Licensing

1. ABDC has 27 distribution centers in the United States. 5/12 Tr. at 149:7-9 (Zimmerman).

2. The distribution center that services Cabell and Huntington is located in Lockbourne, Ohio. *See* 5/12 Tr. at 149:23-150:2 (Zimmerman).

3. Each ABDC distribution center is registered by DEA and licensed by the appropriate state entity to distribute controlled substances. *See* 5/13 Tr. at 152:20-153:5; 171:3-17 (Zimmerman).

4. The Lockbourne distribution center is registered by DEA and licensed by the State of West Virginia. *See* 5/13 Tr. at 171:3-17 (Zimmerman).

5. Plaintiffs offered no evidence that ABDC operated without an appropriate state license and DEA registration at any time.

6. ABDC distributes a full-range of prescription and over-the-counter medications. *See* Ex. AM-WV-02769; Ex. AM-WV-02771; 7/8 Tr. at 42:10-16 (Martens).

7. Prescription opioids made up only a small portion of ABDC's distribution of all medications into Cabell and Huntington. *See* Ex. AM-WV-02768; 7/8 Tr. at 47:23-48:4 (Martens).

8. ABDC's storage of prescription opioids at its distribution centers is consistent with physical security requirements set by the DEA. *See* 5/13 Tr. at 166:14-169:7 (Zimmerman). Plaintiffs presented no evidence that ABDC failed to maintain adequate physical security over controlled substances in any of its distribution centers.

9. ABDC distributes to customers in Cabell and Huntington who are registered with the DEA and licensed by the State of West Virginia. There is no evidence that ABDC distributed to any pharmacy that was not registered with the DEA and licensed by its state regulator. *See* 5/11 Tr. at 69:12-16 (McCann); 5/12 Tr. at 65:14-18 (McCann); 5/26 Tr. at 131:21-23 (Rafalski).

10. ABDC reports all prescription opioids it ships to the DEA through the ARCOS database that DEA houses. *See* 5/17 Tr. at 119:9-13 (May); *see also* 5/13 Tr. at 153:6-14 (Zimmerman); 5/11 Tr. at 72:14-73:1 (McCann). Additionally, since 2007, ABDC reports each and every controlled substances sale it made (whether it was an ARCOS-reportable controlled substance or not) within two days after each shipment is made. *See* 5/17 Tr. at 119:14-25 (May); *see also* 5/13 Tr. at 153:15-19 (Zimmerman).

II. The Evidence Relating to ABDC's Diversion Control Program Does Not Establish Unreasonable Conduct

A. Between 1998 And 2007, ABDC Operated A Nationwide Suspicious Order Monitoring Program Approved By DEA

1. Bergen Brunswig's Pre-1998 SOM Program And The Genesis Of The Work With DEA To Develop The 1998 Program

11. Prior to 1998, ABDC's predecessor, Bergen Brunswig, operated a suspicious order monitoring (SOM) program that detected and reported suspicious orders to the DEA in two separate ways. 5/13 Tr. at 174:6-16 (Zimmerman); Ex. AM-WV-00781 at 9.

12. First, Bergen Brunswig developed a model Excessive Purchase Report. Ex. AM-WV-00781 at 9. The Report listed total customer purchases for the month that exceeded pre-determined multiples of the average monthly purchases of Bergen Brunswig's total customer base. Ex. AM-WV-00781 at 9. Each of Bergen Brunswig's distribution centers sent Excessive Purchase Reports on a monthly basis to DEA field offices. 5/13 Tr. at 174:6-16 (Zimmerman).

13. Second, Bergen Brunswig distribution center employees reported suspicious orders by calling their local DEA field office. 5/13 Tr. at 174:6-16 (Zimmerman). Bergen Brunswig made on average 12,000 calls annually to DEA field offices across the country reporting customer orders of controlled substances that it believed met the suspicious order criteria set forth in § 1301.74(b). 5/13 Tr. at 47:3-24 (Zimmerman); Ex. AM-WV-00781 at 9. Nearly every order reported telephonically also was included in the month-end Excessive Purchase Report sent to DEA. Ex. AM-WV-00781 at 9.

14. During this period of time, some DEA field offices conveyed to Bergen Brunswig that they were "extremely upset" with the daily phone calls and told Bergen Brunswig to either limit the number of calls or report suspicious orders in a different way. 5/13 Tr. at 47:3-24 (Zimmerman); Ex. AM-WV-00781 at 9-10.

15. In response to this feedback from different DEA field offices, Mr. Zimmerman, on behalf of Bergen Brunswig, reached out to DEA to discuss implementation of a more efficient system for reporting suspicious orders—one that would benefit both the company and DEA. 5/13 Tr. at 47:3-24 (Zimmerman); Ex. AM-WV-00781 at 9-12.

2. Between 1996 and 1998, Bergen Brunswig Worked with DEA to Develop A New Program For Identifying And Reporting Suspicious Orders

16. On September 30, 1996 Mr. Zimmerman wrote to Thomas Gitchel, the Chief of the Liaison and Policy Section at DEA, suggesting that Bergen Brunswig work with DEA to develop a new "suspicious order reporting program that would provide better quality information to DEA in a more efficient manner" by detecting and reporting suspicious orders electronically. Ex. AM-WV-00781 at 9-12.

17. ABDC's proposal to DEA detailed the type of information about the suspicious orders that was to be included in the Excessive Purchase Reports:

> The summary report would show the customer name, address, DEA Number, Item Description, NDC Number, Order Date, Active Ingredient Volume Ordered, Active Ingredient ***Shipped*** and Customer "Allowance" (i.e. average of customers' prior four months orders).

Ex. AM-WV-00781 at 10 (emphasis added).

18. On October 29, 1996, Mr. Gitchel responded to Mr. Zimmerman's proposal, confirming the information that would be included in the Reports:

> As proposed, the summary report would include the customer's name, address and DEA number; a description of the item ordered; the NDC number; date ordered; active ingredient volume ordered and ***shipped***; and the customer's "allowance" or average order."

Ex. AM-WV-00781 at 7 (emphasis added).

19. DEA also understood what information would not be included in the Report. Notably absent from the proposal was any suggestion that the Report would include any narrative explanation as to why any particular order was included on the Report, and DEA never requested that the Report include such information. *See* Ex. AM-WV-00781 at 7-12; *see also* ABDC-Specific Findings ¶ 34, *infra*.

20. For the next two years, Bergen Brunswig—working together with DEA—continued to develop and test the new SOM program. 5/12 Tr. at 219:9-13 (Zimmerman); Ex. AM-WV-00781 at 2-3, 7-8. Bergen Brunswig's Valencia, CA distribution center began testing with the LA-DEA field office on March 1, 1997; Bergen Brunswig's Corona, CA distribution center began testing with the Riverside DEA field office on April 1, 1997; Bergen Brunswig's Hawaii distribution center began testing with the Hawaii DEA field office May 1, 1997; and Bergen Brunswig's Orlando distribution center began testing with the Tampa DEA field office on June 1, 1997. Ex. AM-WV-00781 at 2.

21. Bergen Brunswig and DEA agreed that the new program would set thresholds that applied a default multiplier of three to a customer's four-month purchasing average. 5/13 Tr. at 55:1-17 (Zimmerman).

22. But the new program "was completely flexible for however the DEA wanted to best utilize that information to prevent diversion." 5/13 Tr. at 46:3-21 (Zimmerman).

23. To accomplish that, the program permitted, and Bergen Brunswig encouraged, DEA field offices to adjust the default multiplier for any given drug family, as needed. 5/13 Tr. at 55:1-17 (Zimmerman). Some field offices asked that the default multiplier to be

doubled to six—i.e., that the threshold for reporting orders be higher, not lower. *Id.* at 55:11-56:6 (Zimmerman).

24. DEA field offices also could adjust the frequency (daily, weekly, monthly, quarterly) of Bergen Brunswig's submission of Excessive Purchase Reports. 5/13 Tr. at 46:3-21 (Zimmerman).

25. During the testing phase, Bergen Brunswig made several changes to the proposed new SOM program at the direction of the DEA field offices that were participating in the testing. Ex. AM-WV-00781 at 2-3.

26. However, DEA never told Bergen Brunswig that orders identified as suspicious should not be shipped. 5/13 Tr. at 49:3-10 (Zimmerman).

27. Mr. Prevoznik confirmed that DEA provided input on the design of Bergen Brunswig's suspicious order monitoring program, tested the program, and was very pleased with how the suspicious order monitoring program was being run. *See* Prevoznik, 5/17/2019 Dep. at 1127:13-16, 1127:19-1128:3, 1129:6-8, 1129:12-13, 1129:15-20, 1129:23-24.

3. In 1998, DEA Approved Bergen Brunswig's Newly Developed Suspicious Order Monitoring System In Writing

28. On July 23, 1998, Patricia M. Good, DEA's Chief of the Liaison and Policy Section of the Office of Diversion Control, officially approved the new nationwide SOM program. Ex. AM-WV-00781 at 1 (ABDC-produced version); Ex. AM-WV-02658 (DEA-produced version).

29. Ms. Good wrote to Bergen Brunswig stating:

> This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal regulation.

Ex. AM-WV-00781 at 1 (ABDC-produced version); Ex. AM-WV-02658 (DEA-produced version).

30. DEA's approval is also highlighted at the bottom of the copy of the letter produced by DEA—which includes an internal DEA stamp stating "subject: approve suspicious order monitoring system." Ex. AM-WV-02658 (DEA-produced version).

31. Mr. Prevoznik agreed that DEA approved the implementation of the system that Bergen Brunswig designed. *See* Prevoznik, 5/17/2019 Dep. at 1134:20-23, 1135:2-10, 1139:10-16.

32. DEA's approval letter lauded the new program's Excessive Purchase Reports, stating that "DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion

which is not only useful overall, but is also responsive to the needs of individual DEA offices." Ex. AM-WV-00781 (ABDC version); Ex. AM-WV-02658 (DEA produced version).

33. When Bergen Brunswig and Amerisource Health merged in 2001, the newly formed company—AmerisourceBergen—adopted and used the Bergen Brunswig DEA-approved SOM program across all of ABDC distribution centers nationwide until it enhanced the program in 2007. 5/12 Tr. at 192:9-11 (Zimmerman); 5/17 Tr. at 189:1-10 (Mays).

34. Prior to April 2007, DEA never told ABDC that it should not ship suspicious orders or that ABDC should enhance or otherwise modify the suspicious order reports ABDC was sending to DEA. *See, e.g.*, 5/13 Tr. at 196:19-22 (Zimmerman); 5/18 Tr. at 193:12-194:2, 195:12-196:2 (Mays).

B. In The Early 2000s, ABDC Trained DEA Diversion Control Investigators At ABDC's Richmond, Virginia Distribution Center

35. Between 2003 and 2005, Mr. Mays trained approximately 200 DEA diversion investigators at ABDC's Richmond, Virginia distribution center. 5/18 Tr. at 164:17-165:4 (Mays).

36. These training sessions, which included a tour of ABDC's distribution center and an ABDC-led presentation, educated future DEA diversion investigators about the wholesale pharmaceutical distribution industry and provided an exemplar of how registrants achieved and maintained regulatory compliance. 5/18 Tr. 167:2-6 (Mays); *see also* Ex. AM-WV-00782 at 4-5; Ex. AM-WV-00785 at 4-5; Ex. AM-WV-00786 at 3.

37. Importantly, each training session included an overview of ABDC's DEA-approved SOM program, and described the program's timeframes (daily, weekly, monthly) for reporting suspicious orders. *See, e.g.,* Ex. AM-WV-00785 at 22.

38. DEA officials in attendance, including Thomas Prevoznik, never said anything critical of these reporting methods or otherwise indicated that they were inconsistent with the suspicious order regulation. 5/18 Tr. at 183:9-20 (Mays) ("... I don't recall any of – in any of the sessions ever even being offered a recommendation or told to change anything or that anything was wrong.").

39. Mr. Mays gave this presentation at least five times over the course of 2003-2005—including in October 2005 (after the August 2005 DEA "Distributor Initiative" meeting discussed below)—and not once did anyone from DEA ever tell him that his presentation about suspicious order reporting was incorrect. 5/18 Tr. at 164:17-19, 183:9-20 (Mays).

40. To the contrary, DEA conveyed its appreciation of ABDC's presentation and its willingness to help train future diversion control investigators and, in October 2004, the DEA presented ABDC with a certificate of appreciation in recognition of its

contribution to drug enforcement and to DEA's training program. 5/18 Tr. at 180:23-181:14 (Mays) ("Q. Okay. And what was your understanding as to why they gave you an award? A. It was just to – it was in – you know, it was appreciation for all of the training that we had been doing over the years and during that specific time frame for the diversion investigators.").

41. Mr. Prevoznik agreed that these training sessions were a "valuable experience" for DEA diversion investigator trainees. Prevoznik, 5/17/2019 Dep. at 1140:12-16; 1144:12-14;1144:6.

42. Mr. Prevoznik further recognized that ABDC received a certificate of appreciation in 2004 for these trainings, and agreed that ABDC was deserving of that recognition. Prevoznik, 5/17/2019 Dep. at 1146:7-9; 1146:11-14; 1146:16.

C. ABDC Met With DEA In August 2005

43. In 2005, DEA convened individual meetings with distributors, referred to as the "Distributor Initiative." These meetings were "started in response to the Internet pharmacy issue." *See* Mapes 7/11/2019 Dep. at 129:15-130:2; 130:8-10.

44. ABDC's meeting took place on August 10, 2005 at DEA headquarters in Washington, D.C. Ex. P-09112 at 1.

45. Mr. Mays participated for ABDC and Mike Mapes and Kyle Wright participated for DEA. Ex. P-09112 at 1.

46. The meeting related exclusively to the growing internet pharmacy issue, and was cordial and cooperative. 5/18 Tr. at 193:1-5 (Mays).

47. DEA provided ABDC with information, materials, and suggested tools to help with investigations of possible illegal internet pharmacies. Ex. AM-WV-01079 at 1; 5/18 Tr. at 193:6-194:18 (Mays).

48. The materials provided by DEA included a questionnaire entitled "Internet Pharmacy – Decision Questions," which consisted of twelve questions designed to help identify customers engaged in illegal internet activity. Ex. P-09112 at 17-18.

49. While DEA did not mandate that ABDC include this questionnaire in its due diligence program, ABDC did so (as described below). 5/18 Tr. at 194:9-18, 198:25-199:12 (Mays).

50. This meeting related to internet pharmacies. *See* 5/18 Tr. at 193:1-5 (Mays).

51. During this meeting, DEA did not indicate that ABDC had failed, or was failing, to meet its regulatory obligations (as they relate to internet pharmacies or otherwise). 5/18 Tr. at 195:12-196:2 (Mays).

52. In fact, DEA did not say anything to ABDC about its SOM program in general, let alone tell ABDC that it should revise its programs or policies, or even that it was required to implement the tools related to internet pharmacies DEA discussed at the meeting. *See generally* 5/18 Tr. at 193:1-196:2 (Mays); Ex. P-09112 at 1-2; Ex. AM-WV-01079 at 1.

53. And DEA never suggested that ABDC should not ship suspicious orders. 5/18 Tr. at 193:12-194:2 (Mays).

54. Mr. Mays testified that if DEA had raised any such issues or concerns, he would have immediately shared that message to his colleagues and initiated an action plan. 5/18 Tr. at 195:20-24 (Mays).

55. ABDC followed up with DEA through a September 19, 2005 conference call that included Mr. Mays, Mr. Mapes, and others from ABDC. Ex. AM-WV-01079 at 1; 5/18 Tr. at 198:3-9 (Mays).

56. During that conference call, Mr. Mays explained that the company had begun developing procedures to address the problem of illegal internet pharmacy sales. Ex. AM-WV-01079 at 1.

57. Like the August 10, 2005 conversation, this discussion related only to internet pharmacies; DEA did not say anything suggesting that it believed ABDC was failing to meet its regulatory obligations. 5/18 Tr. at 198:3-24 (Mays).

58. The documentary evidence corroborates Mr. Mays' testimony about the distributor initiative meeting. Mr. Mays' contemporaneous written summaries of the August 10, 2005 meeting and September 19, 2005 conference call corroborate his trial testimony. Ex. AM-WV-01079 at 1.

59. Mr. Mapes' contemporaneous written summary of the August 10, 2005 meeting likewise corroborates Mr. Mays' testimony. Ex. P-09112 at 1-2. That summary, which lists the topics addressed and issues discussed at the meeting, makes ***no*** mention of any discussion of ABDC's method of reporting suspicious orders or practice of shipping suspicious orders and confirms that the only topic discussed at the meeting was internet pharmacies. Ex. P-09112 ("The purpose of the meeting was to address illegal domestic internet pharmacy problem and their source of supply.").

D. ABDC Took Action After Its Meeting With DEA In 2005

60. Following the meeting, ABDC developed and implemented CSRA 2.12: Possible Excessive/Suspicious Order Review—a new robust policy to help DEA with the growing illegal internet pharmacy problem. 5/18 Tr. at 198:25-205:23 (Mays); Ex. AM-WV-01079 at 1-11.

61. ABDC utilized its Form 590 (a customer questionnaire), which included ***every*** question in DEA's suggested "Internet Pharmacy – Decision Questions" questionnaire. 6/10 Tr. at 19:8-23 (Rannazzisi). ABDC's Form 590 also incorporated several additional

questions not included in DEA's suggested "Internet Pharmacy – Decision Questions" questionnaire. *Id.*; *see also* Ex. AM-WV-01079 at 10-11.

62. ABDC and DEA worked collaboratively to uncover and shut down numerous pharmacies engaged in illicit internet activity. *See* 5/18 Tr. at 201:21-202:14 (Mays).

63. As part of this new policy, ABDC also undertook thorough investigations of other customers, investigating hundreds of customers between October 2005 and August 2007. 5/19 Tr. at 8:1-7 (Mays)

64. ABDC investigators validated registrations and analyzed customers' one-year controlled substance purchase reports, site visit results, photos, Form 590 Questionnaires, and publicly available documents. Ex. AM-WV-01079 at 4-6; 5/18 Tr. at 202:20-205:23 (Mays)

65. Nine of the customers investigated were pharmacies located in Cabell-Huntington. *See* Ex. AM-WV-00714A. ABDC found no indication of diversion for any of these nine pharmacies. *Id*

66. DEA did not require ABDC to undertake any of these measures—instead, ABDC did so voluntarily. 5/18 Tr. at 199:13-20 (Mays).

E. The 2006 "Dear Registrant" Letter Did Not Provide Notice Of Any Potential Deficiencies In ABDC's SOM Program

67. On September 27, 2006, Mr. Rannazzisi sent all distributors, including ABDC, a letter addressed simply to "Dear Sir or Madam." Ex. P-00032 at 9-12.

68. Plaintiffs—and Mr. Rannazzisi—have tried to suggest that the letter provided some sort of notice to distributors that there were deficiencies in their SOM programs. The letter, however, does not support that assertion. The letter did not say that excessive purchase order reports were not the type of suspicious order reports required by the regulations; and it does not say that distributors should not ship suspicious orders.

69. Nor did the letter say anything that would suggest that DEA was withdrawing its approval of ABDC's 1998 program or that there was something wrong with its approved SOM program. Mr. Zimmerman explained why he reasonably believed that a "Dear Registrant" letter—which was not addressed specifically to ABDC, but instead distributors generally—did not override DEA's 1998 written approval of ABDC's SOM program or provide a basis for ABDC to believe it needed to modify that program. 5/12 Tr. at 219:9-25 (Zimmerman).

70. Moreover, Mr. Rannazzisi's letter stated that "DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion." Ex. P-00032 at 10. That assertion, coupled with the fact that the letter said nothing about not shipping orders reported as suspicious or offered any criticism of the use of excessive purchase reports, undermines any conclusion that the letter put ABDC on notice that there was anything wrong with its approved SOM program.

F. Prior To 2007, ABDC Shipped Suspicious Orders, But Did Not Ship Orders It Believed Would Be Diverted

71. Prior to 2007, ABDC, along with the rest of the distributor industry, shipped orders deemed suspicious. Indeed, DEA knew—the entire time—that ABDC was shipping orders it deemed suspicious. *See* 5/13 Tr. at 186:4-25 (Zimmerman).

72. At the time, this made sense because every order ABDC fails to ship affects legitimate patients' ability to obtain medication prescribed to them by a licensed doctor. *See* 5/13 Tr. at 186:22-25 (Zimmerman) ("Again, we, we reported our orders that we felt were suspicious, but we would ship the – we shipped the order not to impact patient care and the supply channel."); *see also* 5/17 Tr. at 35:6-8 (May) ("So, if a delivery does not arrive at a pharmacy where a patient was intending to get their medication, it certainly can impact them, yes.").

73. However, even before 2007, ABDC did ***not*** ship orders that it concluded were likely to be diverted. *See, e.g.*, 5/12 Tr. at 203:11-17 (if ABDC knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them"); 5/13 Tr. (Zimmerman) at 187:1-5 ("Now, that isn't to say that there's not an order that we would, we would just ship anything. So, I mean, there are instances where we get something that we won't ship because we just don't feel comfortable, you know. There are unique circumstances.").

G. In Response To Guidance From DEA, ABDC Enhanced Its Diversion Control Program In 2007, And DEA Effectively Approved The Program

1. ABDC Worked With DEA To Develop An Enhanced Diversion Control Program And Resolved The ISO Without Admitting Any Wrongdoing Or Paying A Fine

74. On April 19, 2007, DEA issued an Immediate Suspension Order ("ISO") for ABDC's Orlando, Florida distribution center. Ex. P-00049.

75. The focus of the ISO was narrow—pertaining to ABDC's Orlando distribution center's distribution of controlled substances to four Florida customers engaged in illicit internet pharmacy activity. *See* Ex. P-00049; *see also* 5/19 Tr. at 23:2-16 (Mays); 5/13 Tr. at 190:25-191:3 (Zimmerman). There is absolutely no evidence that a single pill shipped by any of the four internet pharmacies that were the subject of the 2007 ISO made their way into West Virginia, let alone into Cabell or Huntington.

76. And the ISO did not relate to, nor affect, ABDC's distribution of controlled substances from any other distribution center, including the distribution center in Lockbourne, Ohio that serviced the Cabell-Huntington area. 5/19 Tr. at 23:2-16 (Mays).

77. The ISO came without warning and was a complete surprise to ABDC—particularly given ABDC's collaborative relationship with DEA over the years, including the joint effort to address the illegal internet pharmacy issue. 5/19 Tr. at 21:7-25 (Mays).

78. According to Mr. Mays, it also came as a complete surprise to DEA's Mike Mapes, who had met with Mr. Mays at the August 10, 2005 internet pharmacy distributor initiative meeting (and who DEA later assigned to work with ABDC). 5/19 Tr. at 21:7-25 (Mays).

79. Following the August 10, 2005 distributor initiative meeting and prior to April 19, 2007, DEA never once indicated to ABDC that it was displeased with ABDC's efforts to address the illegal internet pharmacy problem. 5/19 Tr. at 19:20-24, 21:7-25 (Mays).

80. As part of the pharmacy investigations ABDC launched after the distributor meeting, discussed above, ABDC had already cut off supplying controlled substances to three of the four pharmacies named in the ISO. 5/12 Tr. at 225:9-21 (Zimmerman); 5/13 Tr. at 192:16-21 (Zimmerman).

81. On April 27, 2007, just three days after it served the ISO, DEA issued an Order of Special Dispensation and Agreement that permitted the Orlando distribution center to ship controlled substances to hospitals, clinics, the Department of Defense, and a limited number of other customer accounts. 5/19 Tr. at 23:23-24:17 (Mays); Ex. P-00009 at 1.

82. DEA also was aware that ABDC had obtained a license on an expedited basis from the Florida Department of Health that enabled the Lockbourne, Ohio distribution center to resume servicing ABDC's Florida accounts with controlled substances. 5/19 Tr. at 24:18-25:24 (Mays).

83. Shortly after the ISO was served, ABDC met with DEA in Washington, D.C. on April 25, 2007. 5/19 Tr. at 26:4-17 (Mays).

84. DEA informed ABDC that it wanted ABDC to implement a program that blocked and did not ship the orders it identified as suspicious. 5/19 Tr. at 26:18-27:3 (Mays).

85. This was the first time DEA had provided such a directive. *See, e.g.*, 5/19 Tr. at 26:23-27:19 (Mays); *see also Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 222 (D.C. Cir. 2017) (noting that "DEA first articulated that [do not ship] requirement in *Southwood*," an administrative decision); Ex. P-23736 (72 Fed. Reg. at 36,501)); 6/9 Tr. at 46:10–18 (Rannazzisi confirming that DEA's guidance "was announced in the final order [in *Southwood*], yes, at that point in time"); 5/26 Tr. at 255:6-96 (Rafalski testifying that "do not ship" guidance "do[es] not appear anywhere in the statute or the regulations").

86. Before this point in time, DEA had not offered any guidance regarding a registrant's obligations regarding suspicious orders that differed from ABDC's DEA-approved program—that is, DEA has never informed ABDC that it should not be shipping suspicious orders or that Excessive Purchase Reports were an insufficient means to report suspicious orders. *See, e.g.*, 5/13 Tr. at 196:19-22 (Zimmerman); 5/18 Tr. at 193:12-194:2, 195:12-196:2 (Mays).

87. Between April 19 and June 22, 2007, ABDC worked hand-in-hand with DEA to develop an enhanced diversion control program. 5/19 Tr. at 29:3-30:2 (Mays).

88. ABDC and DEA had regular meetings at DEA headquarters. 5/19 Tr. at 26:10-28:5 (Mays).

89. And DEA personnel were on-site at ABDC's headquarters working alongside personnel from ABDC's Corporate Security and Regulatory Affairs (CSRA) for weeks in order to assist with the development of the new diversion control program. 5/19 Tr. at 29:3-24 (Mays).

90. ABDC, with direct input and oversight from DEA, designed every aspect of the enhanced SOM program—including customer types, customer sizing, drug product families, peer groups, and use of multipliers. 5/19 Tr. at 45:3-46:8 (Mays).

91. While on site, DEA personnel also provided additional input and guidance. Mr. Mapes, Mr. Wright, and Mr. Davis, at ABDC's request, reviewed due diligence files for several of its high-volume accounts—at least one of which was located in West Virginia—so that DEA could to advise whether these files raised any concerns that would justify ABDC cutting off these customers or warrant referral to DEA for investigation. 5/19 Tr. at 30:11-23 (Mays).

92. DEA never indicated to ABDC that any of these due diligence files were deficient. 5/19 Tr. at 31:2-17 (Mays).

93. Nor did DEA indicate that ABDC's decisions to continue servicing those customers—including the West Virginia customer—were flawed or questionable. To the contrary, DEA told ABDC that it had done everything it could have done in terms of due diligence for these customers, including for certain "high volume" customers. 5/19 Tr. at 30:11-31:13 (Mays).

94. DEA and ABDC resolved the Orlando matter through a Settlement and Release Agreement in very short order—a little more than two months after the ISO was served—on June 22, 2007. Ex. P-00009.

95. The Agreement did not include any fine or financial penalty. Ex. P-00009; 5/19 Tr. at 36:2-5 (Mays). In fact, ABDC has never paid a fine to the DEA. 6/10 Tr. at 24:13-16 (Rannazzisi).

96. The Agreement stated that it was not "an admission of liability by AmerisourceBergen" and "AmerisourceBergen expressly denies the DEA's allegations." Ex. P-00009 at 1; 5/19 Tr. at 36:6-8 (Mays).

97. ABDC (with DEA's input and guidance, as discussed above) designed and implemented a new diversion control program, including an enhanced SOM program that would—for the first time in this industry—block and not ship suspicious orders. *See* ABDC-Specific Findings ¶¶ 87-90, *supra*.

98. The Agreement further required that that the Orlando distribution center's DEA-registration would be reinstated only after DEA "conduct[ed] reviews of the functionality of AmerisourceBergen's diversion compliance program ("Compliance Reviews") at up to five distribution centers of AmerisourceBergen." Ex. P-00009 at 3.

99. The Compliance Reviews and audits were thorough—taking several days to complete and including DEA's review of the order review process at the distribution center level. 5/19 Tr. at 34:1-11 (Mays).

100. DEA also audited ABDC's order review process at the corporate level, looking, for instance, at the due diligence documents investigators relied on when adjudicating orders. 5/19 Tr. at 34:15-35:2 (Mays).

101. Each of these Compliance Reviews passed muster and, as a result, DEA permitted ABDC to file a renewal application for the Orlando distribution center's registration—and DEA renewed the registration in August 2007. 5/19 Tr. at 35:17-36:1 (Mays); 6/10 Tr. at 29:3-30:4 (Rannazzisi).

102. This single incident more than 14 years ago was quickly resolved—with ABDC working closely with DEA—without a finding or admission of liability and without the imposition of a fine. And after that, according to Mr. Rannazzisi, who was in charge of Diversion Control and repeatedly emphasized his own knowledge about distributors during his tenure, ABDC has not even "come up" since 2007—14 years ago. 6/8 Tr. at 72:6-19 (Rannazzisi).

2. ABDC's Enhanced Diversion Control Program Was Effectively Approved By DEA In 2007

103. Given DEA's extensive involvement in the design and implementation of ABDC's enhanced diversion control program (including its enhanced SOM program), ABDC understood that DEA's return of the Orlando distribution center registration signaled effective approval of ABDC's enhanced program. 5/19 Tr. at 38:22-39:7 (Mays).

104. DEA's approval and endorsement of ABDC's 2007 diversion control program was further confirmed at DEA's own Pharmaceutical Industry Conference in Houston, Texas on September 11-12, 2007. *See generally* Ex. DEF-WV-02191 (DEA website); DEF-WV-00001.

105. There, Mr. Zimmerman, alongside DEA's Mr. Mapes, made a presentation to the industry on ABDC's enhanced diversion control program. 5/13 Tr. at 198:7-205:15 (Zimmerman); Ex. DEF-WV-00001; Mapes 7/11/2019 Dep. at 179:3-9 (Mr. Mapes noting that he and Mr. Zimmerman were on stage together presenting ABDC's new program).

106. ABDC understood that DEA viewed ABDC's new enhanced program as the industry standard, and DEA wanted other distributors to implement the same or similar program—and DEA's own website confirms this. Ex. DEF-WV-02191 (DEA website); Ex. DEF-WV-00001; 5/19 Tr. at 40:7-12 (Mays); 5/20 Tr. at 157:6-158:5

(Mone – Cardinal Health) ("Q. Now, what is your understanding of what happened at the conference? A. My understanding of what happened at the conference was that a competitor had presented in conjunction with the DEA and explained their new electronic system for reporting suspicious orders and that the expectation of the DEA had changed relative to when Suspicious Order Reports would be sent to DEA.").

107. Mr. Mapes' testimony about this presentation was clear: DEA asked ABDC to present at this conference because ABDC's newly developed system was compliant with the CSA. Mapes, 7/11/2019 Dep. at 178:11-16, 178:24-179:1; 181:24-182:2, 182:9-182:18.

108. A Cardinal representative who attended the conference said that "DEA referred to the ABC program as the new industry standard." Ex. CAH-WV-00374; *see also* (Reardon –of Cardinal Health), 11/30/2018 Dep. at 528:19-24 ("Q. Tell the jury what you remember about the (ABC) presentation. A. That essentially this was going to be the new standard for the industry with respect to how suspicious orders were monitored, reported and handled); Ex. CAH-WV-00372 (Cardinal representative's handwritten notes on presentation Chris Zimmerman gave to industry in 2007).

109. The handwritten notes of Steve Reardon, Cardinal's representative at the 2007 industry conference, reveal that ABDC's use of a 3x multiplier was disclosed during Mr. Zimmerman's presentation—a presentation which included a DEA representative on stage with Mr. Zimmerman as this information was disclosed. *See* Ex. CAH-WV-00372 at 4 (handwritten notes from Mr. Reardon noting "6 months sales Avg x 3" when discussing "OMP Item Family and Threshold").

110. The presentation at the 2007 conference confirms that DEA understood that ABDC had been shipping suspicious orders before it implemented its 2007 SOM program. Mr. Zimmerman and Mr. Mapes' presentation on ABDC's new program emphasized DEA's new interpretation of the suspicious order regulations. Specifically, Mr. Zimmerman and Mr. Mapes reviewed the industry's shift away from the historical "ship and report" approach, explaining that distributors had been reporting suspicious orders after they had been shipped and were now identifying, investigating and reporting suspicious orders before they were shipped. Ex. DEF-WV-00001; Ex. DEF-WV-02191 at 2.

111. Neither Mr. Mapes, nor anyone else from DEA, ever took issue with Mr. Zimmerman's description of past practices. 5/13 Tr. at 205:16-24 (Zimmerman); 6/10 Tr. at 35:4-24 (Rannazzisi).

112. ABDC gave a similar presentation in 2009 when DEA asked ABDC to join DEA at a conference to explain how the program was functioning. 5/13 Tr. At 205-206; Ex. DEF-WV-00002 (2009 presentation).

3. ABDC's 2007 Enhanced Diversion Control Program

113. ABDC implemented its enhanced diversion control program nationwide in June 2007. The program reported, rejected and did not ship suspicious orders. 5/19 Tr. at 31:18-

32:18 (Mays). Thus, ABDC already had stopped shipping orders identified as suspicious ***before*** Mr. Rannazzisi sent his December 2007 "Dear Registrant" letter—which Plaintiffs say put distributors on notice of the "no ship" guidance. *See* Ex. P-00032 at 3.

114. The 2007 program consisted of five "buckets" of activities that monitor suspicious orders and guard against diversion, which continue to be the cornerstones of the program through present day. 5/17 Tr. 29:2-30:12 (May).

First: Enhanced Suspicious Order Monitoring Program

115. ABDC's enhanced program, as effectively approved by DEA, monitors and reports suspicious orders as follows: ABDC created peer groups so it could compare like customers to like customers—*i.e.*, retail to retail, hospital to hospital. *See* 5/17 Tr. at 85:6-86:13 (May).

116. ABDC organized controlled substances into drug families, and "sized" customers into small, medium, or large. 5/17 Tr. at 86:15-87:24, 203:21-204:4 (May).

117. ABDC also created new thresholds for each type and size of customer for each drug family, using a multiplier of three for ARCOS-reportable controlled substances. *See generally* 5/17 Tr. at 203:14-204:4 (May).

118. A computer program processes all controlled substances orders to determine if they exceeded the customer's threshold for that particular drug family. 5/17 Tr. at 31:14-32:9 (May).

119. Orders that hit the thresholds—considered "orders of interest"—are subject to human review and evaluation (using a totality of circumstances test comprised of many factors) to determine if the order met the statutory definition of "suspicious." 5/17 Tr. at 31:14-32:9, 36:11-39:6 (May).

Second: New Customer Due Diligence

120. ABDC required all new pharmacy customers, except for chain customers, to complete a Form 590 during an on-site visit. *See* Ex. DEF-WV-02191 at 2 (DEA website); 5/19 Tr. at 38:13-18 (Mays).

121. After that, a CSRA (diversion control) team member reviewed and verified the customer's responses. *See generally* 5/19 Tr. at 19:14-16 (Mays).

Third: Ongoing Customer Due Diligence

122. ABDC implemented a "Do Not Ship List," which includes customers to which ABDC will no longer ship controlled substances and customers ABDC declined to onboard after new customer due diligence investigations. 5/17 Tr. at 120:1-13 (May).

123. Customers are added to the List as a result of information ABDC learned either through its own investigations or through other sources. *See generally* Ex. AM-WV-00601.

124. Since 2007, ABDC has added almost 800 customers to its "Do Not Ship List" nationwide. *See generally* Ex. AM-WV-00601.

125. In the normal course, CSRA communicates directly with a customer to inquire about its purchasing history or conducts a site visit. 5/17 Tr. at 26:23-27:16 (May).

126. CSRA holds weekly meetings to analyze the previous week's suspicious orders, including the drug family, quantity, and other metrics related to each suspicious order. 5/17 Tr. at 39:15-40:5 (May).

127. Since approximately 2009, ABDC's ongoing customer due diligence efforts generated monthly trend reports containing a list of all customers purchasing controlled substances and data points that the diversion control team used to track and review controlled substance purchasing. 5/17 Tr. at 96:15-24; 101:7-16 (May). This suite of reports included both the Order Monitoring Program (OMP) size report and product specific drug trend reports. *See* Ex. AM-WV-00406; Ex. AM-WV-00398.

128. The OMP size report compared each customer's purchase of controlled substances to its purchase of all products and identified the percentage of controlled substances purchased by that customer over time. *See* Ex. AM-WV-00406; 5/17 Tr. at 96:1-8 (May).

129. The drug trend reports identified each customer's month over month controlled substance purchases for specific products like oxycodone and hydrocodone and also provided a monthly average for the five to six month time period covered by each report. *See* Ex. AM-WV-00398; 5/17 Tr. at 100:10-20 (May).

Fourth: Policies and Procedures

130. ABDC revised and supplemented its policies and procedures to reflect the enhancements it made to its diversion control program in 2007. 5/17 Tr. at 28:2-14 (May).

131. When ABDC has made subsequent revisions to the program, its policies and procedures were revised accordingly. 5/17 Tr. at 28:2-14 (May).

Fifth: Training

132. ABDC trains all employees involved in the Diversion Control Program, including associates at the distribution center and CSRA diversion control investigators. 5/17 Tr. at 28:16-29:1 (May).

133. ABDC also trains its sales staff. 5/17 Tr. at 28:16-29:1 (May).

134. Since 2007, training programs have been revised and enhanced to reflect the changes in ABDC's diversion control program. *See generally* 5/17 Tr. at 74:9-23 (May).

H. ABDC Continues To Take A Proactive Approach And Constantly Reviews, Adjusts, And Enhances It Diversion Control Program

1. ABDC's Enhanced Diversion Control Program

135. In March 2014, ABDC hired David May, a 30-year veteran of the DEA. 5/14 Tr. at 16:2-17:2 (May).

136. Mr. May has oversight of the day-to-day management of the ABDC's Diversion Control Team. *See* 5/14 Tr. at 16:2-17:2 (May).

137. He also has primary responsibility for and oversight of all interactions with the DEA and state regulatory bodies as related to diversion control and suspicious order monitoring. *See* 5/14 Tr. at 20:20-22:14 (May).

138. In 2014, ABDC began using Pharma Compliance Group, a compliance consulting company made up of former DEA diversion investigators and special agents, for certain pharmacy audits and investigations. 5/14 Tr. at 55:23-56:22 (May).

139. Also in 2014, ABDC engaged FTI Consulting to evaluate its diversion control program, including its SOM program. 5/14 Tr. at 54:18-55:14, 63:18-64:3 (May).

140. ABDC sought to identify a more comprehensive, user-friendly way to best utilize the data it collected from customers both for adjudicating orders and conducting due diligence. *See generally* 5/14 Tr. at 54:18-55:14, 67:20-25 (May).

141. Between 2014 and 2015, ABDC and FTI developed, tested, and refined enhancements to ABDC's SOM program. 5/14 Tr. at 54:18-55:14 (May).

142. The resulting Revised SOM program (typically referred to by ABDC in the normal course as the "Revised OMP") incorporated user-friendly dashboards that visually present many advanced analytics, including customers' purchase history, and trends and developments related to drug use at the national, state, and local levels. *See, e.g.*, 5/17 Tr. at 50:10-55:11, 58:8-63:22, 65:8-68:13 (May).

143. Dashboards are supported by essentially the same voluminous amounts of information and data that has been available to CSRA investigators since 2007; the presentation of this data facilitates decision-making by diversion investigators on both order adjudication and ongoing customer due diligence efforts. *See, e.g.*, 5/17 Tr. at 93:25-94:17 (May).

144. On May 25, 2018, ABDC requested a meeting with DEA to discuss how ABDC's Revised SOM program could "better serve the diversion control objectives of the Drug Enforcement Administration ("DEA") and combat the opioid crisis." Ex. AM-WV-00640.

145. With two complete years of data in the books following the 2015 enhancements to the SOM program, ABDC believed it was an appropriate time to meet with the DEA to review the results of the enhancements and "determine the suspicious order reporting approach which best serves the diversion control objectives of the DEA." Ex. AM-WV-00640.

146. Although DEA initially agreed to meet with ABDC and review its Revised SOM program, DEA subsequently cancelled and never rescheduled. 5/17 Tr. at 93:10-93:16 (May).

I. ABDC Conducted Adequate Due Diligence Of Its Customers

147. The ABDC witnesses whom Plaintiffs called in their case-in-chief described ABDC's customer due diligence program, how the program evolved over the years, and provided testimony specific to customers in Cabell and Huntington.

148. Mr. Mays provided detailed and extensive testimony on the investigations ABDC conducted between October 2005 and August 2007—a program ABDC put in place after the 2005 distributor initiative meeting. 5/18 Tr. at 202:20-205:23 (Mays).

149. As part of that program, ABDC investigators validated and analyzed customers' one-year controlled substance purchase reports, site visit results, photos, Form 590 Questionnaires, and publicly available documents. 5/18 Tr. at 202:20-205:23 (Mays); Ex. AM-WV-01079.

150. Mr. Mays further testified regarding the new program developed in 2007—which included customer due diligence—with input from the DEA. 5/19 Tr. at 29:3-32:22 (Mays).

151. Mr. Zimmerman similarly explained the improvements ABDC made to its due diligence program in 2005 and 2007, as well as ABDC's due diligence policies and procedures generally. 5/13 Tr. at 189:23-190:13 (Zimmerman) (improvements made in 2005); 194:2-12 (enhancements made in 2007).

152. Mr. May explained ABDC's customer due diligence, including its use of Tableau files to track and analyze all available data regarding every individual customer who purchased controlled substances, as well as nationwide trends. *See, e.g.*, 5/17 Tr. at 28:16-29:1; 50:10-55:11; 58:8-63:22; 65:8-68:13; 93:25-94:17 (May).

153. Since 2009, ABDC also utilized OMP size reports and drug trend reports as part of its ongoing due diligence efforts. *See* Ex. AM-WV-00406; Ex. AM-WV-00398; 5/17 Tr. at 96:1-8; 100:10-20 (May). The OMP size report compared each customer's purchase of controlled substances to its purchase of all products and identified the percentage of controlled substances purchased by that customer over time. *See* Ex. AM-WV-00406; 5/17 Tr. at 96:1-8 (May). The drug trend reports identified each customer's month over month controlled substance purchases for specific products like oxycodone and hydrocodone and also provided a monthly average for the five to six month time period covered by each report. *See* Ex. AM-WV-00398; 5/17 Tr. at 100:10-20 (May).

III. There Is No Proof Of Unreasonable Conduct In Cabell Or Huntington

154. The evidence shows that the due diligence described above was conducted in Cabell/Huntington, as well. *See* ABDC-Specific Findings ¶¶ 147-153, *supra*.

155. There is no evidence that ABDC ever: failed to conduct adequate due diligence on its customers in Cabell and Huntington; failed to report a suspicious order made by a Cabell or Huntington customer; shipped a suspicious order to a Cabell or Huntington pharmacy; shipped controlled substances to a Cabell or Huntington pharmacy that was not registered with the DEA; shipped controlled substances to a Cabell or Huntington DEA-registered pharmacy that the DEA had warned ABDC not to supply; or shipped a controlled substance into Cabell or Huntington that was diverted.

156. ABDC distributed to approximately 32 customers in Cabell and Huntington. Most of those customers were never mentioned during trial except to provide information on the number of pills they received. For most of ABDC's customers, Plaintiffs presented no evidence relating to any alleged failure on ABDC's part.

157. Plaintiffs focused primarily on 3 customers: Safescript, Drug Emporium, and McCloud Family Pharmacy. But Plaintiffs did not prove unreasonable conduct in relation to ***any*** of these pharmacies.

A. Safescript

158. Plaintiffs focused much of their case on Safescript, a pharmacy that ABDC has not serviced in over fourteen years. But despite the focus placed on it at trial, there was no evidence that a single pill from Safescript was diverted; there was ***no*** evidence of any actual harm tied to Safescript; there was ***no*** evidence that the West Virginia Board of Pharmacy took any action against Safescript; there was ***no*** evidence that Safescript ever failed a West Virginia Board of Pharmacy inspection; and there was ***no*** evidence that the owner of Safescript, or any pharmacist who worked at Safescript, was ever prosecuted.

159. On top of what was not proven, the evidence did show that ABDC's due diligence of Safescript was adequate.

160. ABDC's CSRA personnel opened the investigation following their ***own*** review of Safescript's hydrocodone purchases in April 2007. Ex. AM-WV-01418; Ex. AM-WV-01444.

161. Mr. Perry, the local account manager, provided a CSRA Form 590 and photographs to ABDC's compliance personnel, and also provided compliance personnel with a detailed description of Safescript. Ex. AM-WV-01444.

162. CSRA personnel then evaluated the due diligence Mr. Perry collected along with its independent online research on Safescript, and concluded that Safescript "did not indicate any type of diversion." Ex. AM-WV-01444.

163. In addition, Mr. Perry—the only trial witness who actually visited Safescript—provided a first-hand account on the pharmacy. He described Safescript as a "normal practice," which had a full line of pharmaceuticals on their shelves and was located in an "okay" part of Huntington. 5/19 Tr. at 184:19-185:8 (Perry).

164. Safescript was also licensed by both the DEA and the West Virginia Board of Pharmacy. 5/19 Tr. at 185:9-18 (Perry).

165. And Mr. Perry, who visited Safescript approximately every other week for a period of several years, testified that he did not observe any red flags there. 5/19 Tr. at 185:19-187:18 (Perry).

166. With the information obtained from their 2007 investigation, monthly trend reports and other ongoing due diligence efforts, and Mr. Perry's first-hand accounts in hand, ABDC adjusted Safescript's threshold both up and down over the years in response to the pharmacy's needs. *See* 5/18 Tr. at 86:15-22 (Mays); s*ee also* Ex. AM-WV-01444; Ex. AM-WV-00406; Ex. AM-WV-00398.

167. Dr. Craig McCann noted that oxycodone purchasing actually dropped after the threshold increase. 5/11 Tr. at 90:21-91:2 (McCann). And Dr. McCann even testified that an ABDC email "seems to have been effective" in lowering Safescript's purchasing. *Id.*

168. ABDC reported to DEA suspicious orders placed by Safescript every year from 2007 to 2011—the same period of time during which thresholds were adjusted. *See* Ex. P-44766.

B. Drug Emporium and McCloud

169. ABDC opened investigations into both Drug Emporium and McCloud Family Pharmacy in 2007. Ex. AM-WV-01410; Ex. AM-WV-01999.

170. Consistent with ABDC's customer investigation program discussed above, Mr. Perry obtained Form 590s and photographs and submitted them to CSRA personnel. Ex. AM-WV-01410; Ex. AM-WV-01999.

171. Mr. Perry testified that he did not observe any "red flags" during his frequent visits to these customers. 5/19 Tr. at 194:10-12 & 16-21 (Perry) (Drug Emporium); 191:17-192:13 (Perry) (McCloud Family Pharmacy).

172. ABDC's investigations concluded that there was no indication of diversion occurring at either pharmacy. *Id.*

173. In addition to records of investigations and monthly trend reports for McCloud and Drug Emporium, ABDC introduced evidence of customer-specific Tableau files for both Drug Emporium and McCloud (files that represented due diligence of these pharmacies from April 2015). Ex. AM-WV-01040E; *see also* 5/17 at 176:6-19 (May).

IV. There Is No Evidence Of Diversion Of Prescription Opioids Shipped By ABDC To Huntington Or Cabell County

174. There is no evidence that any of the orders shipped by ABDC met the definition of a "suspicious order." And the testimony of Plaintiffs' own witnesses controvert even the assertion an order that meets the regulatory definition of "suspicious"—but that lacks any indicia of diversion—is likely to be diverted or cause harm. For instance, Mr. Rafalski agrees that the vast majority of orders meeting the definition of a "suspicious order" are not likely to be diverted. 5/26 Tr. at 214:12–16; Prevoznik Dep. Tr. at 1206:6–1209:7 (testifying that there can be "legitimate" reasons for placing orders meeting the regulatory definition of suspicious including "a new customer base, prescriber, a new doctor's office opened").

175. There also is no evidence of actual diversion in Cabell and Huntington. Mr. Rafalski admitted that he has no opinion that "diversion occurred at the pharmacy level." 5/26 Tr. at 135:8–13 (Rafalski). For his part, Mr. Rannazzisi said he had no knowledge at all on shipments to, let alone diversion in, West Virginia. 6/9 Tr. at 14:6–17 (testifying that he could not identify "any orders in Huntington or Cabell County that [he] believed ... should have been blocked" and that he has "not reviewed any documents related to West Virginia."); 6/10 Tr. at 23:8–9 ("I have no knowledge of any distributions into those counties.").

V. There Is No Evidence That The Volume Of Pills ABDC Shipped To Cabell And Huntington Was Unreasonable

176. ABDC's shipments to Cabell and Huntington were driven by the prescriptions written by licensed doctors. *See* Findings at Part III, *supra*.

177. The overall shipment of *all* prescription medications to Cabell and Huntington were high. *See* 5/6 Tr. at 32:3-33:6 (Gupta) (testifying that West Virginia leads the nation in prescription medications per person).

178. The overwhelming majority of ABDC's distributions to Cabell and Huntington consisted of medications other than opioids, like blood pressure medication, anti-depressants, diuretics, and asthma medication. *See* Ex. AM-WV-02769; Ex. AM-WV-02771; 7/8 Tr. at 42:10-16 (Martens). Prescription opioids made up only a small portion of ABDC's distribution of all medications into Cabell and Huntington. *See* Ex. AM-WV-02768; 7/8 Tr. at 47:23-48:4 (Martens).

179. ABDC's distribution of both opioids and non-opioid medication into Cabell and Huntington trended consistently. *See* Ex. AM-WV-02768; Ex. AM-WV-02770; 7/8 Tr. at 45:2-21 (Martens). For example, ABDC's distribution of all products—opioids and non-opioids alike—peaked in 2009, with the growth of non-opioid shipments outpacing opioid shipments. 7/8 Tr. at 45:2-21 (Martens); Ex. AM-WV-02768; Ex. AM-WV-02770.

180. And there was no evidence that the volume of ABDC's distribution of opioid medications was disproportionate to the volume of its overall shipment of medications.

In fact, ABDC's distribution of non-opioid medications increased at a larger rate and outpaced its distribution of opioid medications. *See* Ex. AM-WV-02768; Ex. AM-WV-02770; 7/8 Tr. at 45:2-21 (Martens).

ABDC-SPECIFIC CONCLUSIONS OF LAW

181. Plaintiffs did not prove that ABDC engaged in actionable conduct (whether defined as unreasonable conduct, intentional conduct, negligent conduct, or unlawful conduct.).

182. To prove their public nuisance claims, Plaintiffs needed to prove that ABDC acted unreasonably in its distribution of opioids to Cabell or Huntington. ECF No. 1294. Plaintiffs did not meet their burden of proof.

183. Plaintiffs did not prove unreasonable conduct with respect to ABDC's shipments of prescription opioids to Cabell or Huntington. Plaintiffs presented no evidence that ABDC ever: failed to conduct adequate due diligence on its customers in Cabell and Huntington; failed to report a suspicious order made by a Cabell or Huntington customer; shipped a suspicious order to a Cabell or Huntington pharmacy; shipped controlled substances to a Cabell or Huntington pharmacy that was not registered with the DEA; shipped controlled substances to a Cabell or Huntington DEA-registered pharmacy that the DEA had warned ABDC not to supply; or shipped a controlled substance into Cabell or Huntington that was diverted or that ABDC believed would be diverted.

184. Plaintiffs did not prove that ABDC acted unreasonably with respect to its diversion control programs or suspicious order monitoring systems. The evidence, in fact, shows that ABDC acted reasonably in designing and operating its diversion control programs and SOMs systems.

185. Plaintiffs also did not prove that the volume of prescription opioids ABDC shipped to Cabell/Huntington was unreasonable. The evidence, in fact shows that the volume of prescription opioids shipped were to Cabell/Huntington customers was based on prescriptions written by doctors based on the then-prevailing standard of care.

186. Because Plaintiffs did not prove unreasonable or otherwise actionable conduct on the part of ABDC, judgment should be entered in favor of ABDC.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

APPENDIX C: CARDINAL HEALTH-SPECIFIC FINDINGS OF FACT AND CONCLUSIONS OF LAW

CARDINAL-HEALTH SPECIFIC FINDINGS OF FACT

1. Cardinal Health's suspicious order monitoring ("SOM") system changed over time as technology, diversion trends, and guidance from the DEA changed, *see* J. Norris 8/7/18 30(b)(6) Dep. Designations at 122:24–123:2, 123:5–7, but Cardinal Health at all times maintained a reasonable system to identify and report suspicious orders in compliance with the Controlled Substances Act ("CSA") and contemporaneous DEA guidance.

2. Cardinal Health has maintained a SOM system since the inception of the CSA. *See* J. Norris 8/7/18 30(b)(6) Dep. Designations at 244:11–245:1.

3. Cardinal Health's various SOM programs have always identified, inter alia, orders that met the regulatory definition of "suspicious." *See* J. Norris 8/7/18 30(b)(6) Dep. Designations at 244:11–245:13.

4. Cardinal Health's various SOM programs have always included knowing its customers. *See* J. Norris 8/7/18 Dep. Tr. at 297:12–14, 297:17–298:2.

I. Cardinal Health's Suspicious Order Monitoring System: Pre-2007

5. From the 1990s until late 2007, Cardinal Health operated a suspicious order monitoring system that was reasonable under the circumstances of the time, including then-existing technology, the requirements of the CSA, DEA guidance, industry custom and practice, and then-existing diversion trends.

6. During that time, Cardinal Health's SOM program was overseen by Steve Reardon, a former law enforcement officer. Starting in about 2005, Mr. Reardon's title was Vice President for Quality and Regulatory Affairs ("QRA"). *See* S. Reardon 11/30/18 Dep. Designations at 410:8–22, 411:1–4, 498:8–21.

7. Mr. Reardon supervised a group of employees with anti-diversion responsibilities in the QRA department, and additional personnel in Cardinal Health's distribution centers also had responsibilities related to anti-diversion. *See* S. Reardon 11/30/18 Dep. Designations at 465:4–15; *id.* at 500:17–23; E. Brantley 11/26/18 Dep. Designations at 150:19–151:6, 151:9–18; *id.* at 360:24–361:3; 5/20 Tr. (Moné) at 171:9–15, 172:8–15.

8. During Mr. Reardon's tenure in charge of anti-diversion efforts at Cardinal Health, Mr. Reardon had the resources necessary to perform QRA's functions. *See* S. Reardon 11/30/18 Dep. Designations at 503:18–22.

9. James Rafalski, the only Plaintiffs' witness to testify specifically about Cardinal Health's systems, never mentioned, much less criticized, the staffing or training of the QRA department under Mr. Reardon's leadership.

10. The components of Cardinal Health's SOM program prior to late 2007 included suspicious order reporting and due diligence on Cardinal Health's pharmacy customers. *See generally* S. Reardon 11/30/18 Dep. Designations at 505:12–508:7; *id.* at 518:1–24.

11. Cardinal Health had a two-step process for complying with the regulatory requirement to report suspicious orders. *See* S. Reardon 11/30/18 Dep. Designations at 506:12–19; E. Brantley 11/27/18 Dep. Designations at 529:8– 530:18; Ex. CAH-WV-00580.00046 (Cardinal Health "DEA Compliance Manual" outlining the company's process for complying with 21 CFR 1301.74(b)).

12. ***First***, Cardinal Health submitted monthly Ingredient Limit Reports ("ILRs") to DEA. *See* S. Reardon 11/30/18 Dep. Designations at 424:19–425:2; Ex. CAH-WV-00580.00046.

    a. The format and parameters for ILRs were developed around 1990 as part of a collaboration between the distributors' trade organization, then called the National Wholesale Druggists' Association ("NWDA"), and DEA. *See* S. Reardon 11/30/18 Dep. Designations at 421:18–422:16; *id.* 507:21–508:1; E. Brantley 11/27/18 Dep. Designations at 521:14–17.

    b. Cardinal Health started creating ILRs around 1994 or 1995. *See* S. Reardon 11/30/18 Dep. Designations at 424:9–425:12.

    c. From the 1990s through 2007, Cardinal Health submitted ILRs on a monthly basis to the local DEA field office overseeing each distribution center. *See* S. Reardon 11/30/18 Dep. Designations at 506:20–23; 5/26 Tr. (Rafalski) at 64:16–65:1.

    d. Each ILR was based on a computer program which monitored customers' controlled substance purchases for a month and compared those purchases to predetermined averages or limits. If a customer's purchase quantities exceeded the established parameters in that month, the customer's activity was printed on the report. Ex. CAH-WV-00580.00046; J. Norris 8/7/2018 30(b)(6) Dep. Designations at 134:15–23.

    e. ILRs included customer names and DEA numbers, quantities of specific substances ordered, and the predetermined ingredient limits. If a customer exceeded the ingredient limit for that month, its total purchases were reflected on the ILR. *See* S. Reardon 11/30/18 Dep. Designations at 507:4–508:1.

    f. The predetermined ingredient limits that were applied and appeared on ILRs were based on a formula received from DEA. *See* E. Brantley 11/27/18 Dep. Designations at 521:14–17; *id.* at 531:20–532:5.

    g. Under that system, Cardinal Health shipped orders that it reported as suspicious or potentially suspicious on ILRs, pursuant to direction it received from DEA. *See* J. Norris 8/7/2018 30(b)(6) Dep. Designations at 133:17–24. Thus, ILRs were generated after the orders had shipped. *See* E. Brantley 11/27/18 Dep. Designations at 368:22–23, 368:25–369:1.

    h. This was standard practice in the industry at the time. *See* Findings ¶¶ 139, 142.

i. Although Mr. Rafalski testified at length about the use of ILRs, he did not opine that there was anything wrong with the general use of those reports or with how Cardinal Health established limits for its customers. *See generally* 5/26 Tr. (Rafalski) at 66:6–73:12.

13. ***Second***, and separately from the ILRs, Cardinal Health distribution center personnel—sometimes called "pickers and checkers"—would, as a matter of course, evaluate orders on a daily basis before they were shipped to customers. They were encouraged to investigate orders that appeared excessive and notify DEA "before the order [wa]s shipped." Ex. CAH-WV-00580.00046; *see also* S. Reardon 11/30/18 Dep. Designations at 428:7–429:14; *id.* at 437:20–438:9, 438:11–24, 439:2; E. Brantley 11/27/18 Dep. Designations at 369:3–11, 369:13–15.

a. Cardinal Health submitted what it called "excessive purchase reports" to DEA reflecting orders identified by distribution personnel as being of unusual size, pattern, or frequency. *See* J. Norris 8/7/18 30(b)(6) Dep. Designations at 134:1–14.

b. Cardinal Health sometimes sought specific guidance from DEA as to how to handle orders that had been flagged in the distribution centers by contacting the local DEA field office. *See* S. Reardon 11/30/18 Dep. Designations at 513:6–13.

c. If DEA told Cardinal Health not to ship an order it identified as excessive, Cardinal Health did not ship that order. *See* J. Norris 8/7/18 30(b)(6) Dep. Designations at 130:20–23, 131:3–10.

14. In addition to reporting suspicious orders through the two processes outlined above, Cardinal Health also conducted due diligence on its customers before 2007, including by obtaining customer licenses and verifying addresses, Ex. CAH-WV-00580.00130, and by conducting additional diligence, including site visits to some customers that appeared on ILRs, E. Brantley 11/27/18 Dep. Designations at 20:10–19. This due diligence, including site visits, was "over and above the requirement" to report suspicious orders. E. Brantley 11/27/18 Dep. Designations at 523:19–524:7.

15. Cardinal Health's SOM program, including its use of ILRs, complied with the DEA's guidance and expectations at the time. *See* Findings ¶ 142; S. Reardon 11/30/18 Dep. Designations at 421:18–422:16.

a. Other companies, as well as DEA, sometimes referred to what Cardinal Health called "ILRs" as "excessive purchase reports." M. Mapes 7/11/19 Dep. Designations at 95:8–19, 95:25–96:11; 5/26 Tr. (Rafalski) 64:10–65:1.

b. Use of ILRs or excessive purchase reports was the industry practice for all companies for more than 30 years. *See* Findings ¶ 139.

c. DEA was aware of this industry practice. *See* Findings ¶ 142.

d. DEA approved the practice of shipping orders that were reported as suspicious. *See* Findings ¶ 142; *see also* Ex. AM-WV-02658 (DEA letter approving ABDC's similar process).

e. DEA was aware of Cardinal Health's process for reporting suspicious orders because DEA reviewed those processes as part of its cyclic audit inspections. Based on DEA's awareness and the fact that DEA never raised an issue with the process, Mr. Reardon understood Cardinal Health to be in compliance with DEA's requirements. *See* S. Reardon 11/30/18 Dep. Designations at 508:2–5, 508:7–20, 508:22–24.

f. To Mr. Reardon's knowledge, DEA never stated during a cyclic audit that Cardinal Health's system for monitoring and reporting suspicious orders was inadequate. *See* S. Reardon 11/30/18 Dep. Designations at 511:8–22.

g. DEA never asked Mr. Reardon for different suspicious order reports than the ones Cardinal Health provided. *See* S. Reardon 11/30/18 Dep. Designations at 514:23–515:5.

h. The words "do not ship" do not appear anywhere in the CSA or its implementing regulations. 5/26 Tr. (Rafalski) 255:6–8.

i. Before 2007, DEA never told Cardinal Health not to ship an order identified as suspicious. 5/26 Tr. (Rafalski) 251:14–25.

16. Mr. Reardon attended a presentation by DEA to Cardinal Health as part of the Internet Pharmacy Initiative on August 22, 2005. Ex. CAH-WV-00472; S. Reardon 11/30/18 Dep. Designations at 517:6–16.

a. DEA's presentation at that meeting did not include guidance or instruction not to ship orders reported as suspicious. Ex. CAH-WV-00472.

b. Following this presentation, Mr. Reardon immediately started developing a process and program to identify and monitor Internet pharmacy activity. *See* S. Reardon 11/30/18 Dep. Designations at 517:17–518:6.

c. Plaintiffs presented no evidence that there were internet pharmacies operating in Cabell/Huntington.

d. Mr. Reardon hired Eric Brantley in 2005 to conduct due diligence site visit inspections of pharmacies based on ILRs. *See* S. Reardon 11/30/18 Dep. Designations at 517:17–518:6; E. Brantley 11/27/18 Dep. Designations at 18:15–24, 20:5–19; *id.* at 522:20–523:5.

e. Mr. Brantley and his team decided whether pharmacy customers posed an unreasonable risk of diversion. If a customer did pose such an unreasonable risk, it was terminated and DEA agent Kyle Wright was notified. *See* S. Reardon Dep. Designations at 519:9–14; E. Brantley 11/27/18 Dep. Designations at 20:5–19; *id.*

at 522:20–523:5. Likewise, when Cardinal Health came to believe a customer might be involved in Internet activity, it discontinued shipments of controlled substances to that customer and reported that customer to DEA. *See id.* at 544:16–21.

f. Mr. Brantley also trained members of Cardinal Health's senior management, sales force, and the QRA team on anti-diversion policies. *See* E. Brantley 11/27/18 Dep. Designations at 547:20–548:7.

17. Cardinal Health understood that DEA approved of the changes to its SOM program in response to the Internet Pharmacy Initiative. *See* S. Reardon 11/30/18 Dep. Designations at 520:1–2, 520:5–8, 520:11–13, 521:15–522:11, 523:3–6, 524: 2–4, 524:7–13, 524:16–525:14, 525:17–20; E. Brantley 11/27/18 Dep. Designations at 548:14–23, 549:1–3, 549:10–12, 549:15–21, 550:3, 550:7–10.

a. Mr. Reardon had conversations in 2006 with Kyle Wright, the DEA agent who received Cardinal Health's notifications of terminated customers. Mr. Reardon understood from those conversations that DEA thought Cardinal Health was headed in the right direction and that Mr. Brantley had established a great working relationship with Mr. Wright. *See* S. Reardon 11/30/18 Dep. Designations at 520:1–2, 520:5–8, 520:11–13.

b. Mr. Wright never told Mr. Reardon or Mr. Brantley that Cardinal Health's anti-diversion program was deficient in any way. *See* S. Reardon 11/30/18 Dep. Designations at 521:11–14; E. Brantley 11/27/18 Dep. Designations at 549:15–21, 550:3, 550:7–10.

c. On April 26, 2007, Mr. Reardon spoke to Mr. Wright by telephone. During that conversation, Mr. Wright indicated that Cardinal Health was "doing the right things and heading in the right direction." Ex. CAH-WV-00363; S. Reardon 11/30/18 Dep. Designations at 521:24–525:50; E. Brantley 11/27/18 Dep. Designations at 550:23–551:11, 551:18–552:9, 552:12–18, 552:23–553:6.

18. In 2006 and 2007, Cardinal Health received letters from Joseph Rannazzisi at DEA purporting to reiterate distributors' obligations under the CSA and reinforcing the distributor initiative meetings. Ex. P-00030; *see* Findings ¶ 142. Cardinal Health complied with the guidance in those letters. See S. Reardon 11/30/18 Dep. Designations at 525:24–526:9.

19. In approximately September 2007, DEA's guidance about suspicious order monitoring to Cardinal Health changed. *See* S. Reardon 11/30/18 Dep. Designations at 527:22–528:3; Ex. P-00069.

a. Mr. Reardon attended the DEA Pharmaceutical Industry Conference on September 11, 2007. *See* S. Reardon 11/30/18 Dep. Designations at 528:4–24; Ex. P-00069.

b. At that conference, AmerisourceBergen and DEA jointly presented a new suspicious order monitoring program that AmerisourceBergen recently had

developed and implemented. Ex. P-00069; App'x B (ABDC Findings) at ¶¶ 104–111.

c. Following that presentation, Mr. Reardon sent the slides from that presentation to colleagues at Cardinal Health and informed them that "DEA is setting a new standard with which we must comply," and that DEA referred to ABDC's program as they presented it as the "new industry standard." Ex. P-00069.

d. This presentation was the first time Mr. Reardon understood DEA to be providing guidance to distributors not to ship orders they reported as suspicious. *See* S. Reardon 11/30/18 Dep. Designations at 529:17–23.

e. Immediately upon his return to Cardinal Health's corporate office following the presentation by ABDC and DEA, Mr. Reardon began creating a new team to develop a new SOM program. *See* S. Reardon 11/30/18 Dep. Designations at 529:24–530:6.

II. Cardinal Health's Suspicious Order Monitoring System: 2008-2012

20. Following its receipt of changed guidance and expectations from the DEA in late 2007, Cardinal Health revised its SOM program to take account of and conform to DEA's guidance and expectations. Cardinal Health implemented that revised program in early 2008 and operated that system until 2012. That version of Cardinal Health's SOM system was reasonable and in compliance with the CSA, DEA's guidance, and industry custom and practice.

21. In December 2007, Cardinal Health hired a well-qualified pharmacist and lawyer, Michael Moné, to enhance and lead its SOM program. Mr. Moné had a depth of experience: he had worked as a practicing pharmacist; a prosecutor for the Florida Board of Pharmacy; an attorney involved in opioid issues in the Florida Attorney General's Office; and the Executive Director of the Kentucky Board of Pharmacy, where he helped create one of the first state Prescription Drug Monitoring Programs. 5/20 Tr. (Moné) at 152:15–16; 152:17–23; 153:9–11, 153:18–21, 153:23–25, 154:10–20.

22. When Mr. Moné took charge of Cardinal Health's SOM program, the company was already in the process of making changes to comply with the DEA's new expectations, as expressed in the Rannazzisi letters and at the industry conference in September 2007, at which the DEA and AmerisourceBergen co-presented its new, approved SOM system. *Id*. at 157:6–8, 157:12–16, 157:19–158:5, 158:22–25, 159:23–160:9. Those new DEA expectations included that suspicious orders were not to be shipped to customers. *Id.* at 159:4–22.

23. Cardinal Health enhanced its SOM system to incorporate the three main components discussed in the DEA-AmerisourceBergen presentation: (1) "Know Your Customer," (2) electronic order monitoring, and (3) investigations. *Id.* at 158:9–17, 173:1–5, 174:6–11, 174:14–20.

24. ***Know Your Customer***. "Know Your Customer" involved thorough evaluation of new customers (i.e., review of detailed questionnaires) and continuing diligence regarding existing customers. *Id*. at 173:1–5, 173:16–17, 173:21–174:1, 182:25–183:25. Approval of new customers was not automatic: Cardinal Health refused to approve certain prospective customers due to diversion concerns. *Id*. at 221:24–222:1.

a. The Know Your Customer process was somewhat different for chain pharmacy stores, as authorized by the DEA at the September 2007 AmerisourceBergen/DEA conference. *See* Ex. DEF-WV-0001 (PowerPoint re: AmerisourceBergen SOM System from September 2007 DEA conference) at .00007 ("[r]etail chain pharmacies are exempted" from "Know Your Customer' Due Diligence investigations"); Ex. DEF-WV-02191 (DEA website summary of September 2007 conference) at .00002 (same).

b. Plaintiffs presented no evidence that Cardinal Health approved a chain-pharmacy store it should not have.

c. Mr. Rafalski opined that Cardinal Health failed to conduct sufficient due diligence of its customers, but he did not review all of Cardinal Health's due diligence files, only some. 5/26 Tr. (Rafalski) at 228:4–9. Nor did Mr. Rafalski identify any specific Cabell/Huntington pharmacy for which he claims Cardinal Health did not do sufficient due diligence.

d. Moreover, the primary basis for Mr. Rafalski's opinion that Cardinal Health did not do adequate due diligence is the absence of files from before 2012. But there is no DEA requirement to retain due diligence files, as Mr. Rafalski acknowledged, 5/26 Tr. (Rafalski) at 269:21–25, and his inference that no due diligence was ever done simply because the company did not retain centralized due diligence records for 9 to 25 years is not supported. To the contrary, Mr. Moné testified that his team investigated every order that exceeded that pharmacy's threshold. 5/20 Tr. (Moné) at 62:18–21 ("[E]very order that triggers is going to have some sort of due diligence.").

e. Cardinal Health also required its sales staff, who visited pharmacy customers regularly, to look for and report any potential signs that diversion might be occurring. 5/21 Tr. (Kave) at 95:9–17. Sales representatives at Cardinal Health received frequent and regular training on anti-diversion and red flags for potential signs of diversions. *Id*. at 70:25–71:04.

25. ***Electronic order monitoring***. With electronic order monitoring, Cardinal Health established customized thresholds (or limits) for each customer and each drug family. 5/20 Tr. (Moné) at 184:17–25, 185:3–7; J. Norris 8/7/18 30(b)(6) Dep. Designations at 226:18–24. This system automatically blocked orders that exceeded a customer's threshold, pending evaluation by the anti-diversion team comprised of in-house pharmacists who reviewed any information that they believed was necessary to make an appropriate assessment. 5/20 Tr. (Moné) at 185:24–186:2, 186:11–187:2. If the anti-diversion team cleared the order after the assessment, the order was shipped. *Id*.

at 63:4–7. If the anti-diversion team determined that an order was in fact suspicious, Cardinal Health reported the order to the DEA and did not ship it. *Id*. at 189:12–16

a. Cardinal Health reported suspicious orders to the DEA consistent with DEA's expectation that a properly-functioning SOM system should not generate a large volume of suspicious orders. 6/7 Tr. (Rannazzisi) at 219:5–220:5.

b. Cardinal Health acted reasonably in setting thresholds. In setting initial thresholds, it segmented customers by type and size. 5/20 Tr. (Moné) at 59:5–60:4. It consulted with experts, including Deloitte, IBM Watson, and a Ph.D. at Ohio State, each of whom concluded that the assumptions underlying the threshold calculations were appropriate. *Id*. at 139:7–17, 143:4–8. Cardinal Health also relied in part on the DEA's Chemical Handlers Manual, which provided a framework for identifying excessive orders of List I chemicals, which include certain controlled substances, using a multiplier. *Id*. at 93:17–94:4, 94:22–25. Over time the anti-diversion team would evaluate thresholds and determine whether or not to make changes to thresholds. *Id*. at 64:22–23, 65:7–14.

c. Mr. Rafalski testified that there is no one particular golden rule for what a threshold should be; it is a decision for the registrant. 5/26 Tr. (Rafalski) at 82:15–83:5.

d. Mr. Rafalski did not criticize the level at which Cardinal Health set the threshold for any of its Cabell/Huntington pharmacy customers.

e. Cardinal Health, under Mr. Moné's direction, also created an Analytics team to support the SOM system in establishing thresholds and running reports. 5/20 Tr. (Moné) at 83:5–9, 174:23–25, 199:1–3.

26. ***Investigations***. The investigations component of Cardinal Health's suspicious order monitoring system involved site visits of pharmacy customers conducted by former police and former DEA-diversion, Medicaid-fraud, and Board of Pharmacy investigators. 5/20 Tr. (Moné) at 174:14–20, 187:13–14, 187:9–188:4, 188:13–22.

27. Cardinal Health adopted comprehensive Standard Operating Procedures ("SOPs") regarding the SOM system, and periodically updated those procedures. *See, e.g.*, Ex. CAH-WV-00001 (SOP for a new retail independent customer survey process); Ex. CAH-WV-00030 (SOP for the new account approval process); Ex. CAH-WV-00745 (SOP to establish SOM threshold limits); Ex. CAH-WV-00743 (SOP for threshold event review, self-verification; decision making and threshold outcome communication); Ex. CAH-WV-00740 (updated SOP for detecting and reporting suspicious orders and responding to threshold events); Ex. CAH-WV-00026 (SOP for on-site investigations); Ex. CAH-WV-00747 (updated SOP for on-site investigations).

a. Cardinal Health trained and tested all employees involved in anti-diversion activities on the SOPs. 5/20 Tr. (Moné) at 192:13–20, 196:13–16. These employees numbered in the hundreds—all employees in the centralized anti-diversion group, QRA more broadly, and in the 26 distribution centers, sales managers, and sales directors.

b. Mr. Rafalski did not criticize the SOPs or the training provided on SOPs by Cardinal Health.

28. During Mr. Moné's tenure in charge of anti-diversion efforts at Cardinal Health, Mr. Moné had the resources necessary to perform the anti-diversion group's functions. 5/20 Tr. (Moné) at 182:12–15.

a. Mr. Moné increased Cardinal Health's anti-diversion staff by hiring, *inter alia,* a Senior Vice President of Supply Chain Integrity and Regulatory Operations, a Vice President, two Directors and six Investigators. *Id*. at 53:1–6, 182:16–18.

b. Mr. Rafalski did not criticize Cardinal Health's levels of hiring or the credentials of the persons hired.

29. From 2007 to 2012 Mr. Moné regularly communicated with the DEA about Cardinal Health's SOM system. *Id*. at 217:21–23, 219:12–16.

a. In early 2009, Mr. Moné met with Barbara Boockholdt (Chief of the Regulatory Section of the DEA's Office of Diversion Control) and several DEA diversion investigators. Over the course of a week, Mr. Moné reviewed with them the company's SOM system, as revamped in light of the DEA's new expectations. *Id.* at 219:17–220:1. That discussion included reviewing the procedures for setting customer thresholds—including any multipliers used—and how Cardinal Health identified and reported suspicious orders. *Id*. at 220:9–23.

b. Cardinal Health shared with DEA its policies and procedures, *id*. at 220:24–221:8, and demonstrated the kinds of reports that could be generated by the SOM system. *Id*. at 221:9–11.

c. At the end of that weeklong meeting, the DEA did not ask Cardinal Health to change the system or fault it in any way. *Id*. at 221:17–23; G. Quintero 12/6/18 Dep. Designations at 90:23–91:13.

d. Following the 2009 meeting, the DEA inspected a number of Cardinal Health distribution centers, doing "a deep dive into the SOM system" for the purpose of verifying that the SOM system worked as indicated. 5/20 Tr. (Moné) at 223:2–4, 223:6–7, 223:22–224:10.

e. At the conclusion of the inspections, the DEA did not identify any flaws in the system, and there is no evidence that the DEA proposed any changes. G. Quintero 12/6/18 Dep. Designations at 90:23–91:13.

f. Mr. Moné continued to be in regular touch with Ms. Boockholdt throughout his tenure. He updated her about changes and improvements in the SOM system, 5/20 Tr. (Moné) at 225:24–226:2, 226:5–11, and expected that she would advise him if the DEA observed any deficiencies in the system. *Id.* at 226:16–227:1.

g. Throughout this period (and all time periods), Cardinal Health reported to the DEA each and every shipment of controlled substances to its pharmacy customers via the ARCOS reporting system. *Id*. at 181:6–14. At no point during Mr. Moné's tenure did the DEA inform Cardinal Health that it believed Cardinal's shipments to any particular Cabell/Huntington pharmacy, or to Cabell/Huntington generally, were excessive. *Id*. at 181:15–20.

h. On multiple occasions Cardinal Health requested, but the DEA declined to provide, ARCOS information reflecting distributions of controlled substances from other wholesalers to Cardinal Health's customers s. *Id*. at 218:2–4, 218:22–24. That information would have enabled Cardinal Health to assess whether a customer was ordering amounts from another distributor above the threshold set by Cardinal Health. *Id*. at 218:6–16.

i. Cardinal Health also asked the DEA to advise it if the DEA had reason to believe that a pharmacy might be engaged in diversion so that Cardinal could investigate further or stop the sale of controlled substances to that customer. The DEA never responded. *Id.* at 218:25–219:10.

30. DEA conducted regular cyclic inspections of Cardinal Health's more than 20 distribution centers, each of which held its own DEA registration. 5/20 Tr. (Moné) at 166:20–22, 167:8, 225:3–14. During these cyclic inspections, the DEA had full access to the company's policies and procedures, as well as customer due diligence files. *Id*. at 225:15–20.

III. Cardinal Health's Suspicious Order Monitoring System: 2012-Present

31. Plaintiffs presented no evidence regarding Cardinal Health's conduct after 2012. There is no evidence that Cardinal Health acted unreasonably in monitoring, reporting, and halting shipment of suspicious orders at any time in the last nine years.

32. In 2012, Todd Cameron assumed responsibility for the company's anti-diversion efforts and enhanced the program again. 5/20 Tr. (Moné) 16:22–25.

33. Cardinal Health developed a new analytical methodology to set thresholds for customers. That methodology calculates how busy a pharmacy is based on the total number of prescriptions it dispenses for all medications. Cardinal Health then uses national pharmacy data purchased from a third-party data aggregation company to determine what a normal dispensing product mix looks like, and then applies that data to the customer's overall prescription count. It further considers information about the specific pharmacy gathered in due diligence to set customer-specific and drug-specific threshold limits. Ex. CAH-WV-00476 ("Enhancing our anti-diversion program" memo); G. Quintero 12/6/18 Dep. Designations at 70:3–74:13.

34. Orders that hit thresholds are held for review by analysts on the anti-diversion team. Analysts first familiarize themselves with background due diligence on the customer, including previous held orders and resolutions thereof, the location of the customer, the customer's class of trade, and comments in the Anti-Diversion Centralization database.

Analysts then review the specific held order, including the drug family, order size, threshold, and accrual amount to determine whether the order should be cleared for shipment or cancelled and reported to DEA. Ex. P-14290_00825 (QRA SOM Customer Analytics General Work Instructions).

35. Cardinal Health implemented what it calls "objective criteria" to quantitatively assess its customers across a variety of data metrics. Cardinal Health collects data about its customers across the objective criteria—which include the percentage of prescriptions dispensed that are for controlled substances and more specifically for opioids—and compares that data to national averages. Ex. CAH-WV-00476 ("Enhancing our anti-diversion program" memo); Ex. P-14290_00884 (Objective Criteria Working Guidelines).

36. Cardinal Health developed the Large Volume Tactical and Analytical Committee ("LVTAC"), which is a group of anti-diversion professionals, including senior leadership, which analyzes and makes decisions about customers that purchase large volumes of controlled substances from Cardinal Health. Ex. CAH-WV-00065 (LVTAC SOP); Ex. CAH-WV-00564 (Two-person approval SOP).

37. Cardinal Health continues to do regular site investigations of its customers, visiting them in person, looking for any signs of possible diversion, and requesting and analyzing pharmacy data. Ex. P-14290_00860 (QRA Investigations SOP); G. Quintero 12/6/18 Dep. Designations at 98:24–99:15, 100:12–101:3.

38. This data-driven, analytical methodology requires orders to be reported to DEA anytime they hit a threshold and cannot be promptly cleared for shipment based on due diligence information on hand—even if Cardinal Health doesn't believe that diversion is occurring at the pharmacy. *See* G. Quintero 12/6/18 Dep. Designations at 84:15–85:15, 94:10–97:10; Ex. CAH-WV-00104 (Detecting and Reporting Suspicious Orders SOP); Ex. CAH-WV-00562 (DMQ Working Guidelines); Ex. P-14290_00825 (QRA SOM Customer Analytics General Work Instructions). Accordingly, Cardinal Health submitted more suspicious order reports for customers in Cabell County and the City of Huntington starting in 2012, compared with previous years. Ex. P-42071.

39. After making these enhancements, Todd Cameron presented the program to DEA on multiple occasions. *See* G. Quintero 12/6/18 Dep. Designations at 93:9–19.

40. There has been no DEA enforcement action against any Cardinal Health distribution center based on shipments of controlled substances since 2012.

IV. Cardinal Health's Wheeling, West Virginia Distribution Center

41. Cardinal Health has more than 20 distribution centers nationwide. 5/20 Tr. (Moné) at 167:6–9.

42. Virtually all of Cardinal Health's shipments of oxycodone and hydrocodone to Cabell/Huntington since 1996 came from a single distribution center located in

Wheeling, West Virginia. 5/10 Tr. (McCann) at 93:7–14; 5/12 Tr. (McCann) at 61:12–17.

43. The Wheeling, West Virginia distribution center has been registered with DEA at all relevant times. 5/20 Tr. (Moné) 193:20–23; 193:24–194:5.

44. Plaintiffs presented no evidence that Cardinal Health's Wheeling, West Virginia distribution center was ever out of compliance with either the company's SOM system or DEA regulations.

a. DEA's 2008 and 2012 enforcement actions were not taken against the Wheeling distribution center.

b. DEA's 2008 and 2012 enforcement actions did not involve systemic failures of Cardinal Health's SOM program; they involved issues with a limited number of customers serviced by other distribution centers.[14]

c. There is no evidence that the Wheeling, West Virginia distribution center shipped prescription opioids to customers that it knew or had reason to believe were not filling legitimate prescriptions. 5/20 Tr. (Moné) at 180:11–16.

d. DEA never advised Cardinal Health that its shipments to Cabell/Huntington pharmacies, or to any specific pharmacy, were excessive. 5/20 Tr. (Moné) at 181:15–25.

V. Cardinal Health's Distributions to Cabell/Huntington

45. Cardinal Health's distributions to Cabell County and Huntington were reasonable, and there was no indication that they were outside of established norms. 7/9 Tr. (MacDonald) at 45:15–19.

46. John "Tri" MacDonald, accepted by the Court as an expert in the field of data analytics related to the pharmaceutical supply chain, analyzed Cardinal Health's shipments of controlled and non-controlled substances into Cabell County and Huntington. 7/9 Tr. (MacDonald) at 16:11–13, 43:16–19.

47. The DEA has stated that it is normal for a distributor to observe a ratio of up to 20 percent controlled substances to 80 percent non-controlled substances in its pharmacy shipments, and that there are instances when a higher percentage of controlled

[14] The 2008 Settlement Agreement concerned shipments to internet pharmacies from distribution centers in Auburn, WA; Lakeland, FL; Swedesboro, NJ; and Stafford, TX. 5/20 Tr. (Moné) at 165:20–166:22. The 2012 Settlement Agreement concerned only the Lakeland, FL distribution center and four Florida customers, *id.* at 228:6–13, two of which Cardinal Health had terminated before the DEA filed its enforcement action. *Id.* at 229:18–230:1.

substances can also be appropriate for a particular pharmacy. 7/9 Tr. (MacDonald) at 43:21–44:5.

48. 85% of Cardinal Health's distributions to its retail pharmacy customers in Cabell County and Huntington between 2006 and 2018 were for non-controlled substances, 7/9 Tr. (MacDonald) at 44:23–45:07, and only 7.1% of its distributions were for opioid-related medications. *Id.*

49. Jesse Kave was a sales representative at Cardinal Health from 2006 to 2018, and his territory included West Virginia. 5/21 Tr. (Kave) at 63:3–5, 64:13–24. He looked for and reported red flags during his visits to customers. *Id*. at 104:2–11. He never ignored signs of diversion or prioritized making sales over his anti-diversion responsibilities. *Id*. at 95:9–21.

50. Of Cardinal Health's 37 Cabell/Huntington customers, the only specific one that Plaintiffs focused on at trial was T&J Enterprises, Inc., doing business as The Medicine Shoppe, located in Huntington ("Medicine Shoppe"). But there was no evidence of any diversion occurring from Medicine Shoppe and no evidence that Cardinal Health failed to report or block shipment of any suspicious orders placed by Medicine Shoppe.

    a. Mr. Rafalski did not testify about any specific pharmacy, including Medicine Shoppe, and Plaintiffs offered no expert testimony that Cardinal Health acted unreasonably with regard to Medicine Shoppe.

    b. Dr. McCann testified about the volumes shipped to Medicine Shoppe, 5/10 Tr. (McCann) at 133:16–134:14, and Plaintiffs introduced documentary evidence that they argued suggested due diligence failures with regard to the pharmacy.

    c. Plaintiffs argued that the due diligence file for Medicine Shoppe was thin, but the file was hundreds of pages, including material back to 2008 when Medicine Shoppe first became a Cardinal Health customer. Ex. P-42116. The file contained several Anti-Diversion Customer Profiles and information regarding overall controlled substances percentages, volumes of particular categories of drugs, the number of previous threshold events, and overall purchase data by month for that drug family. *Id.*

    d. Plaintiffs also suggested that Cardinal Health did not perform a site visit quickly enough in the face of a request by QRA, but Cardinal Health conducted a full site visit within two months of the request (in August 2012). During that visit, the site investigator found no evidence of diversion. Ex. CAH-WV-00770; 5/20 Tr. (Moné) at 215:23–216:20. The site visit report included explanations for the pharmacy's increased purchases of oxycodone, including that "prescribers in the area prefer oxycodone 15 mg and 30 mg strengths for pain management" and "the pain management population consists of a high number of coal miners and truckers with job related injuries." Ex. CAH-WV-00770 at Section 2. It also concluded that the pharmacist-in-charge understood his corresponding responsibility, only filled controlled substance scripts for local residents and local prescribers, and took

advantage of the State's prescription monitoring program to ensure that patients filling controlled substance scripts did not appear to be engaged in diversion. *Id.* at Section 5.

e. The only people who testified at trial with any knowledge of Medicine Shoppe were former Cardinal Health employees Michael Moné and Jesse Kave. Mr. Kave, the sales representative who called on Medicine Shoppe for 12 years, testified that he knew the pharmacists there and found them to be professional and that he never witnessed signs of diversion at Medicine Shoppe. 5/21 Tr. (Kave) at 107:19–109:8.

f. Medicine Shoppe remains a licensed pharmacy in good standing with the State of West Virginia and the DEA.[15]

CARDINAL HEALTH-SPECIFIC CONCLUSIONS OF LAW

51. To prove their public nuisance claims, Plaintiffs had to establish, at a minimum, that Cardinal Health acted unreasonably. Dkt. 1294.

52. Plaintiffs failed to meet their burden of proof. They did not prove by a preponderance of the evidence that Cardinal Health acted unreasonably in its distributions of prescription opioid medications to Cabell/Huntington.

a. Plaintiffs presented no evidence that Cardinal Health failed to maintain the physical security of the prescription drugs in its possession.

b. Plaintiffs presented no evidence that Cardinal Health distributed prescription opioid drugs to an unlicensed pharmacy in Cabell/Huntington or one about which the DEA, Board of Pharmacy, or any law enforcement agency had raised a concern.

i. Plaintiffs' expert, Dr. McCann, who reviewed Cardinal Health distribution data, is not aware of any shipment from Cardinal Health to a Cabell/Huntington pharmacy not registered with the DEA and licensed by the Board of Pharmacy. 5/12 Tr. (McCann) at 65:14–18.

ii. Dr. McCann is also not aware of any shipment from Cardinal Health to a Cabell/Huntington pharmacy without an order placed by that pharmacy for that shipment. 5/12 Tr. (McCann) at 65:19–23.

[15] License Number SP0550702, https://www.wvbop.com/public/verify/details-business.asp. The Court can take judicial notice of the Board of Pharmacy's public licensure verification. *Jacobus v. Huerta*, 2013 WL 673233, at *7 n.8 (S.D.W. Va. Feb. 22, 2013), *report and recommendation adopted*, 2013 WL 1723631 (S.D.W. Va. Apr. 22, 2013), *aff'd*, 540 F. App'x 208 (4th Cir. 2013) ("The court may take judicial notice of factual information located in postings on governmental websites.").

c. Plaintiffs presented no evidence that Cardinal Health approved a customer it should not have or failed to terminate a customer that it should have.

d. Plaintiffs presented no evidence that any of Cardinal Health's customers were diverting prescription opioids, much less that Cardinal Health knew that.

e. The weight of the evidence establishes that Cardinal Health at all times acted reasonably in designing and operating a suspicious order monitoring (SOM) system to monitor pharmacy orders.

    i. Plaintiffs presented no evidence that Cardinal Health ever shipped an order to any Cabell/Huntington pharmacy that it believed would be diverted. S*ee* S. Reardon 11/30/18 Dep. Designations at 534:9–14 (testifying that in his "experience at Cardinal Health over 25 years" he did not "ever see Cardinal Health ship an order that [he] believed would be diverted"); *accord* M. Hartman 11/15/18 Dep. Designations at 371:12–15; E. Brantley 11/27/18 Dep. Designations at 559:10–14.

    ii. Plaintiffs presented no evidence of any particular order that Cardinal Health shipped to a Cabell/Huntington pharmacy that it should not have.

    iii. As set forth in the above Findings of Fact, the weight of the record evidence is that Cardinal Health at all times designed and operated a SOM system in accordance with industry standards, the CSA, and DEA guidance.

f. The record evidence establishes that the volume of prescription opioids shipped by Cardinal Health to its 37 Cabell/Huntington pharmacies was not facially unreasonable because Cardinal Health distributed the amount of pills that were prescribed by doctors in Cabell/Huntington who were acting in good faith according to the then-prevailing standard of care. *See* Findings ¶ 44.

g. Because Plaintiffs failed to prove that Cardinal Health's conduct was an unreasonable interference with a right common to the general public, they failed to prove their nuisance claims, and the Court will enter judgment in favor of Cardinal Health.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

APPENDIX D: MCKESSON-SPECIFIC FINDINGS OF FACT AND CONCLUSIONS OF LAW

MCKESSON-SPECIFIC FINDINGS OF FACT

I. McKesson's Operations & Licensing

1. McKesson has 28 distribution centers in the United States. *See* 5/25 Tr. (Oriente) at 13:1–3.

2. The distribution center that services Cabell/Huntington is located in Washington Court House, Ohio. *See* 5/25 Tr. (Oriente) at 15:15–20.

3. Each McKesson distribution center is registered by DEA and that registration is renewed annually. *See* 5/25 Tr. (Oriente) at 13:4–13.

4. McKesson's distribution centers are also licensed by the State of West Virginia to distribute controlled substances in the state. *See* Ex. MC-WV-02149 (license compilation); 5/25 Tr. (Oriente) at 15:21–16:24.

5. Since 2014, the State of West Virginia has renewed McKesson's license to operate in the state 150 times. *See* Ex. MC-WV-021250 (license); Ex. MC-WV-02149 (compilation of 149 licenses).

6. Plaintiffs offered no evidence that McKesson operated without an appropriate state license and DEA registration at any time. *See supra* Findings ¶ 4.

7. McKesson distributes a full-range of prescription and over-the-counter medications, including products such as antibiotics and blood pressure medicine. *See* 5/25 Tr. (Oriente) at 10:19–25.

8. Prescription opioids constitute only about 4% of the medications stored at and shipped from McKesson distribution centers. *See* 5/25 Tr. (Oriente) at 11:5–10.

9. While housed at distribution centers, prescription opioids are stored by McKesson in line with physical security requirements set forth by DEA.

   a. McKesson stores Schedule II controlled substances in a reinforced cement vault, similar to a bank vault. *See* 5/25 Tr. (Oriente) at 11:11–19.

   b. McKesson stores Schedule III through Schedule V controlled substances in a locked cage. *See* 5/25 (Oriente) at 11:20–23.

   c. McKesson maintains cameras at its distribution centers, including in the cage and vault, to observe handling and packaging of controlled substances. *See* 5/25 Tr. (Oriente) at 12:9–17.

   d. McKesson restricts access to the cage and vault and only permits entry for a limited set of approved employees. *See* 5/25 Tr. (Oriente) at 12:9–17.

10. Plaintiffs presented no evidence that McKesson failed to maintain adequate physical security over controlled substances in any of its distribution centers.

11. At all times, McKesson has blocked orders that it believed were likely to be diverted. Mr. Oriente testified that McKesson has always "manual[ly] block[ed]" orders that it identified as likely to be diverted. *See* 5/25 Tr. (Oriente) at 48:4–10.

II. McKesson's Limited Shipments and Small Market Share

12. Since 2004, McKesson has held a "Pharmaceutical Prime Vendor" contract with the U.S. Department of Veterans Affairs. *See* 5/25 Tr. (Oriente) at 25:14–26:1; *see also* Ex. MC-WV-02074 (contract in effect 2004–2012); Ex. MC-WV-02062 (contract in effect May–August, 2012); Ex. MC-WV-00918 (contract in effect 2012–2020); Ex. MC-WV-00917 (current contract).

13. Pursuant to this contract, McKesson services the Herschel "Woody" Williams Veterans Affairs Medical Center ("V.A. Medical Center") located in Cabell/Huntington. *See* 5/10 Tr. (McCann) at 86:11–87:11; Ex. P-44711 (summary of data from Dr. McCann) at .00025.

14. Over three-fourths of all oxycodone and hydrocodone that McKesson shipped to Cabell/Huntington went to the V.A. Medical Center.

    a. From 2004–2018, McKesson's total shipments of oxycodone and hydrocodone into Cabell/Huntington were approximately 23.1 million dosage units. *See* 5/10 Tr. (McCann) at 86:11–16.

    b. Of this 23.1 million dosage units, over 17.6 million dosage units were distributed to the V.A. Medical Center. *See* 5/10 Tr. (McCann) at 86:24–87:11.

    c. McKesson's shipments to the V.A. Medical Center account for 76.1% of its total shipments of hydrocodone and oxycodone into Cabell/Huntington. *See* 5/11 Tr. (McCann) at 168:10–16; 7/8 Tr. (Boberg) at 186:9–16.

    d. Dr. McCann testified that McKesson's shipments to the V.A. Medical Center were "a very material amount of McKesson's distribution" to Cabell/Huntington. *See* 5/11 Tr. (McCann) at 169:6–12.

15. Plaintiffs have taken the position that the 17.6 million dosage units distributed by McKesson to the V.A. Medical Center are irrelevant to their claims.

    a. Plaintiffs introduced no evidence about any diversion or other wrongful activity occurring at the V.A. Medical Center.

    b. Dr. McCann testified that his analyses "focus[ed] only on the retail and chain pharmacies not including the roughly 80 percent of the shipments [from McKesson] that came to the V.A. [Medical Center]." 5/12 Tr. (McCann) at 15:2–7; *see also* 5/11 Tr. (McCann) at 169:6–17, 172:10–173:14.

c. Mr. Rafalski testified that McKesson's shipments to the V.A. Medical Center were not "applicable to the diversion topic," and that consideration of McKesson's shipments to the V.A. Medical Center would not be "prudent." 5/26 Tr. (Rafalski) at 271:16–272:6.

d. For this reason, Mr. Rafalski excluded McKesson's shipments to the V.A. Medical Center from his analysis of Cabell/Huntington shipments. *See* 5/26 Tr. (Rafalski) at 271:12–20.

e. Mr. Rafalski and Dr. McCann did not identify any "flagged" or allegedly "suspicious" orders delivered by McKesson to the V.A. Medical Center. *See* 5/11 Tr. (McCann) at 171:23–173:14; 5/26 Tr. (Rafalski) at 271:12–20.

16. McKesson's shipments to retail pharmacies from 2004–2018 in Cabell/Huntington total 5.2 million dosage units of oxycodone and hydrocodone. *See* 5/10 Tr. (McCann) at 86:11–16. This equates to approximately 371,400 dosage units annually for all retail customers combined.

17. Between 2006 and 2014, the time period for which DEA ARCOS data is available, thirty-eight distributors other than McKesson distributed prescription opioids in Cabell/Huntington. *See* 5/11 Tr. (McCann) at 153:15–24, 154:12–155:2 (identifying thirty-six distributors other than the Defendants).

18. McKesson's share of the retail pharmacy market in Cabell/Huntington was 5.99%. *See* 5/11 Tr. (McCann) at 182:8–15; 7/8 Tr. (Boberg) at 186:17–24.

19. McKesson is sixth in market share among wholesale distributors in its distribution of oxycodone and hydrocodone to retail pharmacies in Cabell/Huntington.

a. Dr. McCann confirmed that there are "five companies that shipped more oxycodone and hydrocodone to Huntington and Cabell than McKesson." 5/11 Tr. (McCann) at 180:20–25.

b. McKesson's market share for retail pharmacies is lower than three wholesale distributors that were not defendants at trial.

20. McKesson's per capita distributions to Cabell/Huntington were lower than its statewide or national per capita distributions. *See* Ex. P-44711 (summary of data from Dr. McCann) at .00025.

a. McKesson's annual dosage units per capita to retail and chain pharmacies was 5.83 in Cabell/Huntington, compared to a per capita rate of 6.90 nationally and 10.66 in the State of West Virginia. *See* Ex. P-44711 (summary of data from Dr. McCann) at .00025; 5/11 Tr. (McCann) at 176:25–177:11.

b. Dr. McCann confirmed that McKesson's annual per capita distribution to Cabell/Huntington was "45 percent lower" than its annual per capita distribution in the State of West Virginia. 5/11 Tr. (McCann) at 177:15–17.

c. Dr. McCann confirmed that McKesson's annual per capital distribution to Cabell/Huntington was "15 percent lower" than its annual per capita distribution nationwide. 5/11 Tr. (McCann) at 177:18–19.

21. McKesson has serviced only a small number of pharmacy customers in Cabell/Huntington over time.

a. McKesson's Retail Sales Manager responsible for Cabell/Huntington, Mr. Ashworth, testified that he currently has "three customers" in Cabell/Huntington. 5/25 Tr. (Ashworth) at 197:25–198:3.

b. Mr. Ashworth testified that, as far back as 2010, he has had a similarly small number of customers in Cabell/Huntington—"[p]robably a couple, two or three." 5/25 Tr. (Ashworth) at 198:4–6.

III. No Evidence of Wrongdoing At Any McKesson-Serviced Pharmacy

22. Plaintiffs presented no evidence of diversion or wrongdoing by any McKesson-serviced pharmacy in Cabell/Huntington.

a. Mr. Rafalski admitted that he has no opinion that "diversion occurred at a pharmacy level" for any pharmacy in Cabell/Huntington, including those serviced by McKesson. 5/26 Tr. (Rafalski) at 135:8–13.

b. Mr. Rafalski admitted that he was not "aware of any pills that were shipped by McKesson … that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription." 5/26 Tr. (Rafalski) at 131:6–10.

c. Mr. Rafalski admitted that he was not "aware of … McKesson ever supplying a pharmacy that was not licensed by the DEA." 5/26 Tr. (Rafalski) at 131:21–23.

d. Mr. Rafalski admitted that he was not "aware of any prescription in this case relating to the defendants [including McKesson] … that was dispensed without a pharmacist present with that pharmacist" exercising his or her "corresponding responsibility." 5/26 Tr. (Rafalski) at 132:24–133:4.

e. Mr. Rannazzisi confirmed that he was not aware of any occasion "where [he] or someone at DEA told … [McKesson] that [it] should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy." 6/9 Tr. (Rannazzisi) at 99:10–16.

f. Mr. Rannazzisi also confirmed that he was not aware of any instance where McKesson "supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA." 6/9 Tr. (Rannazzisi) at 151:19–23.

g. Mr. Rannazzisi further confirmed that he was not aware of any instance where McKesson "supplied prescription opioids to a DEA licensed pharmacy in Huntington or Cabell that the DEA had warned the distributor not to supply." 6/9 Tr. (Rannazzisi) at 151:24–152:3.

23. Plaintiffs offered evidence about only five McKesson-serviced customers in Cabell/Huntington: Medicine Shoppe Pharmacy, Fruth Pharmacy, McCloud Custom Script Pharmacy, and Rite Aid.

A. Medicine Shoppe, Fruth Pharmacy and McCloud Family Pharmacy

24. Plaintiffs presented no evidence beyond shipment volumes in relation to McKesson's distributions to Medicine Shoppe Pharmacy.

a. Plaintiffs presented evidence that from 2006 through 2014, McKesson shipped 1,500 dosage units of oxycodone and hydrocodone to a Medicine Shoppe Pharmacy in Cabell/Huntington. *See* Ex. P-44755 (summary of data from Dr. McCann) at .00006.

b. Dr. McCann, described the volume of McKesson's shipments to Medicine Shoppe Pharmacy as "essentially zero." 5/10 Tr. (McCann) at 183:15–20.

c. Plaintiffs presented no evidence of any wrongful activity or diversion related to McKesson's shipments to Medicine Shoppe Pharmacy.

25. Plaintiffs presented no evidence beyond shipment volumes in relation to McKesson's distributions to Fruth Pharmacy.

a. Plaintiffs presented evidence that over an eight-year period, McKesson distributed a combined 45,700 dosage units of oxycodone and hydrocodone to three locations of the Fruth pharmacy chain. *See* Ex. P-44752 (summary of data from Dr. McCann) at .00006, .000011–.000012.

b. Plaintiffs presented no evidence of any wrongful activity or diversion related to McKesson's shipments to any of these Fruth pharmacy locations.

26. Plaintiffs presented no evidence beyond shipment volumes in relation to McKesson's distribution to McCloud Family Pharmacy in Cabell/Huntington.

a. Plaintiffs presented evidence that from 2015–2016, McKesson distributed a limited amount of hydrocodone and oxycodone to McCloud Family Pharmacy in Cabell/Huntington. *See* Ex. P-44754 (summary of data from Dr. McCann) at .00012, .00015.

b. Plaintiffs presented no evidence of any wrongful activity or diversion related to McKesson's shipments to McCloud Family Pharmacy.

B. Custom Script Pharmacy

27. McKesson serviced Custom Script Pharmacy in Cabell/Huntington from 2010–2013. *See* 5/25 Tr. (Ashworth) at 234:3–6.

28. Custom Script was a low-volume pharmacy.

    a. In total, Custom Script Pharmacy's received 441,100 dosage units of hydrocodone and oxycodone combined from all wholesalers between 2006–2014. *See* Ex. P-44747 (summary of data from Dr. McCann) at .00002.

    b. Dr. McCann testified that this total volume, 441,100 dosage units, placed Custom Script "in the bottom half of pharmacies by volume in Huntington/Cabell." 5/11 Tr. (McCann) at 185:19–25.

29. Custom Script Pharmacy was not a typical retail pharmacy, but instead "specialize[d] in compounding specific medications that aren't available in the marketplace from a distributor like McKesson." 5/25 Tr. (Ashworth) at 234:7–13, 235:11–20.

    a. Because of Custom Script's unique business model, Mr. Ashworth testified that the pharmacy "wouldn't have the normal retail traffic" typical of a retail pharmacy. 5/25 Tr. (Ashworth) at 235:16–20.

    b. McKesson maintained diligence-related documents for Custom Script Pharmacy that likewise noted that "this pharmacy's focus is compounding." Ex. P-13284 at .00010.

30. Because of Custom Script Pharmacy's unique business model, it received most of its pharmaceutical supplies from "bulk powder" suppliers, not from distributors of finished pharmaceutical products like McKesson. *See* 5/25 Tr. (Ashworth) at 234:18–235:1; Ex. P-13284 (McKesson customer questionnaire) at 7 (listing two "bulk powder" suppliers, Freedom and PCCA, as Custom Script Pharmacy's primary suppliers).

31. While a high ratio of Custom Script's purchases from McKesson were controlled substances as compared to other pharmaceutical products, Custom Script's unique business model provides a benign explanation for this high ratio.

    a. Mr. Ashworth testified that because "a lot of their non-control[led substances], [are] compounded, rather than purchased from a supplier like McKesson," this compounding business can "skew the number" of their ratio. 5/25 Tr. (Ashworth) 235:11–20.

    b. McKesson's Director of Regulatory Affairs, Mr. Oriente, testified that in evaluating a customer's controlled substance ratio, it is important to understand "the[] [pharmacy's] business model." 5/25 Tr. (Ashworth) at 142:24–143:14. Mr. Oriente further testified that observing a higher controlled substance purchase ratio

at a pharmacy engaged in "specialty compounding" would not be problematic. 5/25 Tr. (Ashworth) at 143:18–23.

c. McKesson's diligence file for Custom Script Pharmacy shows that McKesson's Director of Regulatory Affairs investigated the controlled purchase ratio and concluded that Custom Script Pharmacy's "volume [is] so low [that] his % is an anomaly" due to his compounding business. Ex. P-13284 (McKesson diligence record) at .00018.

32. McKesson monitored and appropriately adjusted Custom Script Pharmacy's purchasing limit, or threshold, for prescription opioids, based on the pharmacy's changing business model and customer base.

a. Neither Mr. Rafalski nor any other trial witness testified that McKesson set its oxycodone or hydrocodone thresholds for Custom Script Pharmacy at too high a level.

b. On October 7, 2010, Custom Script Pharmacy submitted a request to increase its threshold based on the fact it was expanding beyond "compounding products" and beginning to service new customers, including Cabell Huntington Hospital's oncology clinic and the Hospice of Huntington. Ex. P-13714 (TCR request) at .00001; *see also* 5/25 Tr. (Ashworth) at 237:18–238:23.

c. Based on the information provided by Custom Script Pharmacy, McKesson's Director of Regulatory Affairs approved the threshold change request on October 10, 2010. *See* Ex. P-13712 (McKesson threshold change record) at .00002.

d. McKesson continued to monitor Custom Script's threshold and, in 2013, lowered that threshold when it observed that Custom Script's monthly purchasing had declined. *See* Ex. P-13284 (McKesson diligence record) at .00018 ("Thresh[old] 30,500 never ordered 6,000 so lowered 3.25.13.").

e. In 2013, Custom Script Pharmacy dispensed an average of only 2,000 dosage units or less of hydrocodone and oxycodone per month. *See* 5/25 Tr. (Ashworth) at 245:1–20; Ex. P-13284 (McKesson diligence record) at .00009.

f. McKesson has not shipped any opioids to Custom Script since 2013. *See* 5/25 Tr. (Ashworth) at 234:3–6

33. Although Plaintiffs observe that the name of two physicians appear in Custom Script Pharmacy's diligence files who were subject to disciplinary action by the West Virginia Board of Medicine years later, Plaintiffs presented no evidence at trial of the quantity of prescriptions filled for either physician by Custom Script Pharmacy, much less any evidence that even a single one of those prescriptions were written for anything but legitimate medical need. *See supra* Additional Witness-Specific Findings ¶ 144.

34. Plaintiffs did not present any evidence of diversion or any other wrongful action occurring at Custom Script Pharmacy. *See supra* McKesson-Specific Findings at ¶ 22.

C. Rite Aid Pharmacy

35. McKesson serviced four Rite Aid pharmacies in Cabell/Huntington. *See* 5/11 Tr. (McCann) at 196:8–15 (Dr. McCann's Rite Aid shipments considered "four pharmacies combined").

36. McKesson was a secondary distributor for Rite Aid, which self-distributed nearly two-thirds of all prescription opioids it received in Cabell/Huntington.

    a. Dr. McCann confirmed that Rite Aid received "prescription opioids directly from the manufacturer to distribute to themselves." 5/11 Tr. (McCann) at 196:15–22.

    b. Mr. Oriente explained that McKesson would set lower thresholds for controlled substances that Rite Aid self-distributed, such as hydrocodone, because McKesson operated as a "backup secondary supplier." 5/25 Tr. (Oriente) at 145:23–146:12.

    c. According to Dr. McCann, 63% of the oxycodone and hydrocodone dosage units received by Rite Aid stores in Cabell/Huntington were self-distributed by Rite Aid, while only 37% was distributed by McKesson. *See* 5/11 Tr. (McCann) at 21:8–21.

37. The West Virginia Board of Pharmacy reviewed Rite Aid #968 in Cabell/Huntington and determined that it filled prescriptions only for legitimate medical needs.

    a. Board of Pharmacy inspection records for Rite Aid # 968 from 2005, 2011, 2015, and 2017 each concluded that "all prescriptions appear prescribed for a legitimate purpose." Ex. DEF-WV-01989 (Board of Pharmacy inspection records) at .00005 (question 57), .00019 (question 58), .00038 (question 43), .00087 (question 11); *see also* 5/27 Tr. (Rafalski) at 21:7–25:22.

    b. The Board of Pharmacy also remarked that Rite Aid # 968 was a "GOOD PHARMACY!" Ex. DEF-WV-01989 (Board of Pharmacy inspection records) at .00020.

    c. Mr. Rafalski acknowledged that he had not reviewed these Board of Pharmacy inspection records prior to offering his opinions in this case, and that he did not "have any contrary facts about [Rite Aid #968] … or any Rite-Aid in Cabell/Huntington." 5/27 Tr. (Rafalski) at 26:7–9.

38. Mr. Rafalski did not testify that McKesson's distributions to Rite Aid were in any way wrongful or contributed to diversion.

    a. Mr. Rafalski testified that he was not offering any opinion as to "whether Rite-Aid helped cause the opioid crisis in Huntington and Cabell County." 5/27 Tr. (Rafalski) at 27:14–28:11.

    b. Because Mr. Rafalski could not opine that Rite Aid, which was responsible for nearly two-thirds of all shipments to its stores as a self-distributor, contributed to the opioid crisis in Cabell/Huntington, he necessarily could not opine that

McKesson's minority share of shipments to Cabell/Huntington contributed to the opioid epidemic.

c. When asked, Mr. Rafalski was unable to identify how many Rite Aid stores McKesson serviced in Cabell/Huntington, or whether these Rite Aid stores had below-average, average, or above-average ordering. *See* 5/27 Tr. (Rafalski) at 16:2–4, 17:1–5.

d. Neither Mr. Rafalski nor any other trial witness testified that McKesson set its oxycodone or hydrocodone thresholds for Rite Aid at too high a level.

39. McKesson operated its due diligence program for retail national chain pharmacies, like Rite Aid, differently than its program for independent pharmacies in recognition of the fact that national chain pharmacies have their own corporate regulatory affairs departments that monitor compliance at their stores. *See* 5/25 Tr. (Oriente) at 134:19–24; *see also* Ex. MC-WV-00243 (Controlled Substance Monitoring Program for Retail National Chains).

a. McKesson informed DEA that its program operated differently for retail national chain pharmacies like Rite Aid, and DEA did not express concern about this practice. *See* 5/25 Tr. (Oriente) 106:7–23, 107:6–9, 138:1–9; *see also* Ex. P-42657 (2008 presentation to DEA) at .00009.

40. Rite Aid's ordering was monitored pursuant to McKesson's Controlled Substance Monitoring Program, including being subject to monthly ordering thresholds set by McKesson. *See* 5/25 Tr. (Oriente) at 140:19-25.

a. Mr. Oriente testified that McKesson would adjust Rite Aid's thresholds only "when they were requested" and that "[t]he increase would have been reviewed" prior to approval. 5/24 Tr. (Oriente) at 169:10–170:12.

b. While some Rite Aid stores requested and received a 30% "buffer" in their threshold to account for ordering variation, "[n]ot all Rite Aids received … the additional buffer." 5/24 Tr. (Oriente) at 129:6–20.

c. There is no record evidence that any Rite Aid in Cabell/Huntington received a 30% "buffer."

d. McKesson also told DEA that its "thresholds would be based on a customer's history with a buffer," and DEA did not object to that practice. *See* 5/25 Tr. (Oriente) at 104:2–7; Ex. P-42657 (2008 presentation to DEA) at .00008.

41. Mr. Oriente, has had responsibility for monitoring Rite Aid accounts from 2008 to present. *See* 5/25 Tr. (Oriente) at 139:2–7.

a. In his role, Mr. Oriente was aware that Rite Aid had an internal set of policies and procedures on the filling of controlled substances. *See* 5/25 Tr. (Oriente) at 141:10–14.

b. Mr. Oriente worked directly with members of Rite Aid's corporate regulatory affairs department. *See* 5/25 Tr. (Oriente) at 141:4–9.

c. Mr. Oriente's experience working with Rite Aid led him to conclude that "Rite Aid was conducting their due diligence" in relation to orders by specific Rite Aid stores. 5/25 Tr. (Oriente) at 141:15–24.

d. When McKesson flagged concerns about pharmacies to Rite Aid, Rite Aid reviewed those stores and reported back to McKesson with findings and additional information to resolve McKesson's concerns. *See* 5/25 Tr. (Oriente) at 141:25-142:7.

e. Mr. Oriente testified that Rite Aid would also, at times, raise and report issues to McKesson on its own volition. *See* 5/25 Tr. (Oriente) at 142:8–11.

42. Plaintiffs did not present any evidence of diversion or any other wrongful action occurring at any Rite Aid Pharmacy in Cabell/Huntington. *See supra* McKesson-Specific Findings at ¶ 22.

IV. McKesson's Suspicious Order Monitoring Programs Met Industry Standards and DEA Expectations.

A. ARCOS Reporting

43. McKesson reports all distributions of Schedule II and III prescription opioids to DEA's Automated Reporting of Controlled Substances ("ARCOS") database. *See* 5/25 Tr. (Oriente) at 35:17–36:15.

44. McKesson's submissions to DEA's ARCOS database provide significant detail about each prescription opioid shipment.

a. McKesson's ARCOS reports include information on the individual pharmacies being shipped to. *See* 5/25 Tr. (Oriente) at 36:4–6.

b. McKesson's ARCOS reports include information on the dates of shipments. *See* 5/25 Tr. (Oriente) at 36:7–8.

c. McKesson's ARCOS reports include information on the volume of shipments. *See* 5/25 Tr. (Oriente) at 36:9–10.

45. McKesson's ARCOS reporting has been "constant" since DEA implemented the ARCOS reporting database. 5/25 Tr. (Oriente) at 35:17–36:15.

46. Plaintiffs introduced no evidence at trial of any issues with McKesson's ARCOS reporting for its distributions to Cabell/Huntington or elsewhere.

a. Dr. McCann indicated that more than 99.8% of the transactional data produced by McKesson from 2006 to 2014 was accurately reported through ARCOS. *See* 5/10 Tr. (McCann) at 51:10-21.

B. Section 55 of the Drug Operations Manual

47. Prior to 2008, McKesson operated a SOM program that was set out in Section 55 of McKesson's Drug Operations Manual ("Section 55"). *See* Ex. MC-WV-00451 (Section 55 Manual).

48. Under Section 55, each McKesson distribution center submitted daily and monthly faxes to DEA, called "DU-45" reports, which "listed all suspicious orders identified from [its] customers' purchasing patterns." 5/25 Tr. (Oriente) at 42:17–25; *see also* Ex. MC-WV-02143 (exemplar DU-45 report).

49. Under Section 55, McKesson used an algorithm to identify suspicious orders that it adopted from a SOM program that DEA had previously reviewed and stated was effective.

a. Under Section 55, McKesson identified suspicious orders by using a "three times monthly average for Schedule[] II and III" prescription opioids. 5/25 Tr. (Oriente) at 44:2–14; *see also* Ex. MC-WV-00451 (Section 55 Manual) at .00047.

b. This three-times criteria for identifying suspicious orders was identical to another monitoring system that DEA had reviewed. *See* 5/25 Tr. (Oriente) at 50:3–51:18 (Mr. Oriente testifying as to his understanding that Section 55 was "based on DEA approved guidelines").

c. McKesson's Section 55 Manual includes a copy of the 1984 letter that DEA sent after reviewing this SOM system using a three-times modifier, which stated that the SOM system would "provide effective customer verification and suspicious and/or excess order monitoring system" and "appear[s] appropriate for implementation." Ex. MC-WV-00451 (Section 55 Manual) at .00204–.00205.

d. McKesson reasonably relied on DEA's statements in this 1984 letter, *see* Ex. MC-WV-00451 (Section 55 Manual) at .00204–.00205, and, based on this letter, McKesson informed its employees that "these guidelines [in Section 55] have been accepted by DEA" and "compliance with them is mandatory." *Id.* at 46.

50. McKesson's submission of DU-45 reports met DEA's regulatory requirement that McKesson report orders identified as suspicious.

a. Each DU-45 report included text expressly informing DEA that the submission was made "[p]ursuant to CFR 21 [§] 1301.74(B)" and "reflect[ed] purchases from customers for schedules II-V controlled substance which exceed the monthly average" used by McKesson to identify potentially suspicious orders. *See, e.g.*, Ex. MC-WV-02143 (exemplar DU-45 Report) at .00002.

b. Section 55 of McKesson's Drug Operations Manual states that the "Daily Controlled Substance Suspicious Order Warning Report … can be faxed to your local DEA office before the order is shipped." Ex. MC-WV-00451 (Section 55 Manual) at .00048.

51. At the time these reports were in use, DEA accepted reports that identified all orders in excess of an algorithm ("excessive purchase reports") as compliant with DEA's regulatory directive to report suspicious orders. *See supra* Findings at ¶ 142.

52. DU-45 reports were created and sent by "each distribution center" operated by McKesson. *See* 5/25 Tr. (Oriente) at 43:11–17.

a. McKesson submitted DU-45 reports from each distribution center until early 2009. *See* 5/25 Tr. (Oriente) at 43:1–4.

b. The fact that some DU-45 reports were not still maintained more than a decade after McKesson stopped using this reporting format is not evidence that these reports were not contemporaneously created or sent. *See infra* McKesson-Specific Findings ¶¶ 78–79.

53. Under Section 55, and consistent with then prevailing DEA guidance, McKesson did not systematically block all orders identified as suspicious under DEA's regulatory definition. *See* 5/25 Tr. (Oriente) at 9:2–12; *see supra* Findings ¶ 142.

C. Lifestyle Drug Monitoring Program

54. In 2007, McKesson adopted a Lifestyle Drug Monitoring Program ("LDMP") that was an immediate precursor to McKesson's 2008 Controlled Substance Monitoring Program ("CSMP"). *See* 5/25 Tr. (Oriente) at 59:11–22.

55. The LDMP operated in conjunction with—but did not replace—Section 55. *See, e.g.*, 5/25 Tr. (Oriente) at 43:1–4 (testifying that McKesson submitted DU-45 reports "up to about 2009"), *id.* at 59:11–20 (confirming that the LDMP overlapped with Section 55).

56. Under the LDMP, in addition to continued operation of Section 55 and DU-45 reporting, McKesson conducted additional monitoring of four substances, including hydrocodone and oxycodone. Ex. DEF-WV-01527 (LDMP Manual) at .00003.

a. The LDMP "target[ed] controlled substances that the DEA consider[ed] 'lifestyle' drugs." Ex. DEF-WV-01527 (LDMP Manual) at 3. "Lifestyle drug" was a term McKesson adopted from DEA. 5/25 Tr. (Oriente) at 59:23–60:1.

b. Where any customer's purchases of one of the substances monitored under the LDMP exceeded 8,000, the LDMP set forth a process to conduct additional review of the customer's purchasing patterns, culminating in potentially terminating the customer and reporting that customer to DEA. Ex. DEF-WV-01527 (LDMP Manual) at .00003–.00007.

57. In June 2007, McKesson shared a copy of its LDMP manual with DEA for its review. *See* Ex. DEF-WV-01527 (LDMP Manual with cover letter to DEA) at .00001.

D. Controlled Substance Monitoring Program (2008–2013)

58. In response to shifting DEA sub-regulatory guidance regarding its expectations of distributors, including as related to the blocking of suspicious orders, *see* Ex. P-00033 (DEA letter), Ex. P-00034 (DEA letter), McKesson implemented a new SOM program, the Controlled Substance Monitoring Program ("CSMP"), in May 2008. *See* 5/25 Tr. (Oriente) at 55:10–11, 58:23–59:1; Ex. MC-WV-00381 (2008 CSMP Manual).

59. With the advent of the CSMP, McKesson began automatically blocking all orders that it identified as suspicious. Ex. MC-WV-00381 (2008 CSMP Manual) at .00006; 5/25 Tr. (Oriente) at 9:2–12, 55:12–17.

60. In addition to blocking of all orders identified as a suspicious, Mr. Oriente confirmed that McKesson continued to block all orders that it believed were likely to be diverted. *See* 5/25 Tr. (Oriente) at 55:18–20.

61. In order to identify orders as suspicious and block those orders, McKesson employed a system of setting customer-specific maximum monthly thresholds for each DEA drug base code.

a. Mr. Oriente testified that under the CSMP, a monthly order limit, or "threshold," was determined for each controlled substance base code at each pharmacy. *See* 5/25 Tr. (Oriente) at 62:1–7.

b. Under the CSMP, if a customer ordered above its threshold that order would be automatically blocked and would not be shipped. *See* 5/25 Tr. (Oriente) at 62:8–18

c. Under the CSMP, after a customer met its monthly threshold, all further orders for any product containing that DEA base code were blocked for the remainder of the month. *See* 5/25 Tr. (Oriente) at 74:7–13; Ex. MC-WV-00381 (2008 CSMP Manual) at .00007.

d. There was no process for further review and potential shipment of any order in excess of a threshold. Under the CSMP as operated by McKesson, these blocked orders could not later be released. *See* Ex. MC-WV-00381 (2008 CSMP Manual) at .00007.

62. Thresholds under the CSMP were set in a manner to account for each customer's individual needs and ordering variability.

a. Mr. Oriente testified that thresholds were set on a customer-specific basis in order to account for the individualized nature of that pharmacy customer's business, in recognition of the fact that there is wide variability in needs and business models across McKesson's network of customers (*e.g.*, the V.A. Medical Center has very

different needs than a small retail pharmacy). *See* 5/25 Tr. (Oriente) at 63:18–64:13.

b. Mr. Oriente explained that thresholds were set using a customer's historical purchasing in order to account for that customer's individualized needs and business model. *See* 5/25 Tr. (Oriente) at 63:4–17.

c. In order to account for natural ordering variability, Mr. Oriente testified that McKesson also applied small "buffers" as a reasonable measure to "offset … variability where pharmacies order more or less each month." 5/25 Tr. (Oriente) at 103:17–19.

d. Initially, McKesson notified a customer when it was approaching its threshold. This was to ensure that, if a threshold adjustment was appropriate, McKesson could review a pharmacy's request to modify its threshold before orders to fill legitimate prescriptions were blocked. *See* 5/25 Tr. (Oriente) at 108:9–25.

e. Mr. Ashworth testified that when a customer requested a change in its threshold after receiving notice from McKesson, that customer would still have to satisfy the "whole threshold request procedure." 5/25 Tr. (Ashworth) at 219:9–18.

f. Neither Mr. Rafalski nor any other trial witness testified that McKesson set its thresholds inappropriately or at too high a level when it implemented the CSMP in 2008.

63. McKesson's Regulatory Affairs Department reviewed all customer requests to adjust thresholds after receiving a request from the customer that set for reasons and data supporting the adjustment.

a. Mr. Oriente testified that a customer that wished to have a threshold adjusted would have to submit a TCR form for review by regulatory affairs personnel at McKesson. *See* 5/25 Tr. (Oriente) at 75:18–20; *see also* Ex. P-13714 (exemplar TCR form).

b. Mr. Oriente confirmed that McKesson's Directors of Regulatory Affairs were responsible for approving all TCRs submitted by customers. *See* 5/25 Tr. (Oriente) at 75:18-20. Mr. Oriente testified that each TCR would receive due diligence prior to approval or rejection. *See id.* at 65:18-23.

c. Mr. Oriente testified that, in evaluating a request for an increased threshold, McKesson would receive and consider the customer's dispensing data, as well as the customer's stated reason for the increase. *See* 5/25 Tr. (Oriente) at 75:9-17. McKesson would also request prescriber information as part of its due diligence when necessary. *See* 5/24 Tr. (Oriente) at 69:7-11.

d. Mr. Oriente testified that, in the 2008–2013 time period, the Directors of Regulatory Affairs were able to do their due diligence even if they were busy at times. *See* 5/25 Tr. (Oriente) at 67:15–19. If Mr. Oriente received too many TCR forms to

conduct diligence on them all before the end of a month, then some requests would roll over into the next month. *See id.* at 67:20-68:6.

64. Under the CSMP, McKesson also conducted customer due diligence proactively throughout its relationship with a customer, including during customer onboarding and for existing customers. *See* 5/24 Tr. (Oriente) at 181:10–25; 5/25 Tr. (Oriente) at 65:24–66:8.

65. In the context of onboarding a new customer, McKesson undertook specific diligence to vet that customer prior to approving that customer to purchase controlled substances. *See* 5/25 (Oriente) at 82:11–15.

a. McKesson's 2008 CSMP Manual made clear that each new customer had to undergo a customer onboarding process, including providing information to McKesson about its business practices and that "[a]t no time is there a guarantee, implied or otherwise, that any customer will be able to purchase controlled substances based upon information received during this process." Ex. MC-WV-00381 (2008 CSMP Manual) at .00009.

b. The 2008 CSMP Manual further specified that "[a] complete customer questionnaire is mandatory for every new McKesson customer prior to them receiving controlled substances" and that "it is necessary to obtain past purchasing information" from the customer in order to "understand the new customer[']s current controlled substance purchase requirements." Ex. MC-WV-00381 (2008 CSMP Manual) at .00011, .00013.

c. Mr. Oriente testified that as part of McKesson's onboarding process for new customers, McKesson would administer a customer questionnaire, ask for dispensing data, and do a site visit. *See* 5/25 (Oriente) at 83:7–24.

d. The customer questionnaire required a potential new pharmacy customer to provide information on its licensing status, the identity of its personnel that would handle controlled substances, its average amount of purchases, and its customer base and business model. *See* Ex. MC-WV-00381 (2008 CSMP Manual) at .00011–.00014; *see also* Ex. MC-WV-00185 (template questionnaire).

e. The questionnaire also included a section for a physical inspection completed by a McKesson employee. *See* Ex. MC-WV-00185 (template questionnaire) at .00008; *see also* 5/25 Tr. (Oriente) at 89:10–90:9 (describing physical inspection of new pharmacy customers).

f. In addition to the above diligence, McKesson verified DEA and state licenses of pharmacies as part of its onboarding process. *See* 5/25 Tr. (Oriente) at 86:16-87:3.

66. Under the CSMP, McKesson also conducted ongoing due diligence of its existing customers. *See* 5/25 Tr. (Oriente) at 90:15–91:10, 94:18–24; Ex. MC-WV-00381 (2008 CSMP Manual) at .00015.

a. Mr. Oriente testified that he would proactively review customers and select pharmacies for site visits based on markers such as size, purchasing level, number of blocked orders, or other "red flags." *See* 5/25 Tr. (Oriente) at 92:5-15.

b. "Red flags" are items that McKesson's Regulatory Affairs team would pay attention to as they evaluated customers. However, the presence of a red flag, by itself, does not mean diversion has occurred or will occur. Red flags can be resolved through additional diligence. *See* 5/25 Tr. (Oriente) at 96:6-17.

c. McKesson provided guidance to its employees about the types of "red flags" to look for when evaluating pharmacies. *See*, *e.g.*, Ex. P-12643 (May 2015 McKesson CSMP "Red Flags"). Mr. Oriente testified that "red flags" changed over time "[a]s different diversion trends evolved … and came to light … and [were] added to our red flag list." 5/25 Tr. (Oriente) at 98:16–22.

d. During on-site visits to current customers, McKesson would look for "red flags" such as out-of-state plates on cars, security guards on site, or unusually long lines. *See* 5/25 Tr. (Oriente) at 89:14–21, 93:22–94:17. McKesson would also consider how customers paid for their prescriptions, and the range of products sold by the pharmacy. *See id.* at 94:6–17.

e. Where "red flags" or other issues could not be resolved, McKesson would terminate existing customers. *See* 5/25 Tr. (Oriente) at 94:25–95:5.

67. Under the CSMP, McKesson used a three-level review process to investigate suspicious orders.

a. A Level I review would be conducted for customers who had an order blocked. *See* Ex. MC-WV-00381 (2008 CSMP Manual) at .00007 ("A level 1 review is required for every threshold excursion," resulting in a blocked order); 5/25 Tr. (Oriente) at 77:12–19, 81:1–3 ("Q. Just to orient ourselves … what level would blocking occur at? A. Prior to Level 1.").

b. A Level I review consisted of a McKesson employee contacting a customer to ask why that customer had attempted to order above its threshold, triggering a blocked order. *See* 5/25 Tr. (Oriente) at 81:1–3.

c. If a Level I review resolved suspicions, the order would not be treated as suspicious or reported to DEA. *See* 5/25 Tr. (Oriente) at 78:3-7; Ex. MC-WV-00381 (2008 CSMP Manual) at .00007.

d. Even if a Level I review resolved any suspicions, the ordered item would remained "blocked for the remainder of the month" unless the customers separately submitted a TCR form that was approved by a Director of Regulatory Affairs. *See* 5/25 Tr. (Oriente) at 77:20–24. The two review processes—Level I and TCR review—are distinct. *See id.* at 77:25–78:2; Ex. MC-WV-00381 (2008 CSMP Manual) at .00007 (at the conclusion of a Level I, McKesson will "[c]ontinue to block item

until the beginning of [the] new month," absent a "[r]equest [for] a temporary/permanent threshold change").

e. If the Level I review did not resolve suspicions, then McKesson would escalate the customer to a Level II review. *See* 5/25 Tr. (Oriente) at 78:12–19.

f. A Level II review would involve escalation to a member of the Regulatory Affairs team at McKesson "to do a review of that pharmacy." 5/25 Tr. (Oriente) at 78:24–79:3; Ex. MC-WV-00381 (2008 CSMP Manual) at .00007–.00008.

g. An order could be resolved at a Level II review, but if suspicions remained the order would be escalated to a Level III review. *See* 5/25 Tr. (Oriente) at 79:4–11; Ex. MC-WV-00381 (2008 CSMP Manual) at .00008 ("If after the Level I and Level II reviews have been conducted and the transactions are deemed 'suspicious' a Level III review is necessary.").

h. McKesson's policy manual states, and Mr. Oriente confirmed, that "[u]pon escalation to Level III, ALL control[led substance orders] will be blocked." Ex. MC-WV-00381 (2008 CSMP Manual) at .00008; 5/25 Tr. (Oriente) at 79:12–18 ("[T]he customer would be blocked from all controlled substances."). This includes other controlled substance base codes, in addition to the base code for the order triggering the review. *See id.* at 79:12–18 ("[A]ll controlled substances for that customer, not just that specific base code that was [already] blocked, would be blocked.").

i. Upon reaching a Level III review, McKesson would also notify DEA about the terminated customer and report the customer and its orders as "suspicious." *See* 5/25 Tr. (Oriente) at 79:25–80:9, 80:17–25; Ex. MC-WV-00381 (2008 CSMP Manual) at .00008 ("The customer / transaction(s) are reported to DEA Headquarters as 'suspicious'.").

j. Mr. Oriente testified that Level III reviews and accompanying terminations could happen with or without a preceding Level I or II review. 5/25 Tr. (Oriente) at 95:14–20.

68. McKesson's system of reporting orders in combination with a customer termination, after escalation to Level III review, was consistent with DEA's then-current guidance about suspicious order reporting.

a. In 2007 and 2008, McKesson received guidance from DEA that it understood to mean that DEA wanted McKesson to report fewer suspicious orders. *See* 5/25 Tr. (Oriente) at 55:25–56:21, 58:2–22, 81:16–18.

b. This guidance included notifications from DEA field offices that they wished to stop receiving copies of McKesson's DU-45 reports that listed all orders in excess of an algorithm. *See* Ex. MC-WV-00592 (Buffalo DEA notice to stop submitting DU-45 reports); *see also* 5/25 Tr. (Oriente) at 58:12–15.

c. As a result of DEA's changed guidance, McKesson adopted the CSMP system that reported orders as suspicious at a Level III review, despite having already blocked that order prior to a Level I review. *See* 5/25 Tr. (Oriente) at 81:1–6. As a result, McKesson reported fewer suspicious orders than it blocked during this period of time. *See id.* at 81:7–11.

d. Mr. Oriente confirmed that all suspicious orders "would be blocked" under McKesson's CSMP, even if blocked orders that did not escalate to Level III review were not reported. 5/25 Tr. (Oriente) at 81:12–15.

e. The uncontroverted record evidence establishes that blocking of orders, not reporting, is what prevents diversion. *See supra* Findings ¶ 150.

69. McKesson gave multiple presentations on its CSMP to DEA. These presentations informed DEA about how key elements of the CSMP operated, including the fact that McKesson would not report orders as suspicious until escalation to a Level III review.

a. Mr. Oriente gave a presentation on its CSMP program to DEA in November 2008 in order to make DEA aware of McKesson's new SOM Program and receive feedback. *See* 5/25 Tr. (Oriente) at 101:21-23; 102:4-14; Ex. P-42657 (November 2008 DEA Presentation).

b. Mr. Oriente told DEA that McKesson's CSMP would block orders prior to a Level I review, but that McKesson would not report those orders as suspicious until a Level III review. *See* 5/25 Tr. (Oriente) at 109:19–110:8; Ex. P-42657 (November 2008 DEA Presentation) at .00016.

c. DEA did not express any disagreement to Mr. Oriente upon being told about this three-level reporting process. *See* 5/25 Tr. (Oriente) at 110:2–8.

d. McKesson's Senior Vice President of Distribution Operations, Donald Walker, gave a similar presentation to DEA in July 2008. *See* 5/25 Tr. (Oriente) at 10:14–111:3, 112:1–7; Ex. MC-WV-00397 (July 2008 DEA Presentation).

e. Mr. Walker's presentation also laid out McKesson's three-level reporting structure, that showed blocking of orders occurring prior to Level I review and DEA reporting occurring at Level III review. *See* Ex. MC-WV-00397 (July 2008 DEA Presentation) at .00010–.00012; *see also* 5/25 Tr. (Oriente) at 112:23–113:8.

f. In this same presentation, McKesson told DEA that it would stop submitting DU-45 reports to local field offices. *See* 5/25 Tr. (Oriente) at 113:9-17; Ex. MC-WV-00397 (July 2008 DEA Presentation) at .00013.

70. When McKesson presented its CSMP to DEA, it also told DEA about numerous other aspects of the CSMP with which DEA did not express any disagreement.

a. McKesson told DEA that it would set customer thresholds by using the customer's 12-month purchase history plus a "buffer" of 10%. *See* 5/25 Tr. (Oriente) at 103:3–14. DEA did not indicate disagreement with this procedure. *See id.* at 104:2–7.

b. McKesson told DEA about its on-boarding due diligence procedures, and how those procedures would differ for retail chain pharmacies, like Rite Aid, as compared to independent pharmacies. *See* 5/25 Tr. (Oriente) at 105:15–106:3. DEA did not indicate any disagreement when told by McKesson that it would take a different approach for retail national accounts. *See id.* at 106:4–23, 107:6–9; *see supra* McKesson-Specific Findings ¶ 39.

c. McKesson told DEA that it would notify customers as they approached their thresholds. *See* 5/25 Tr. (Oriente) at 108:2–8; Ex. P-42657 (November 2008 DEA Presentation) at .00015. DEA did not express any concern with this procedure. *See* 5/25 Tr. (Oriente) at 108:2–8.

E. Controlled Substance Monitoring Program (2013–present)

71. From 2013 through the present, McKesson has continued to systematically block all suspicious orders, and it has also blocked all orders it identified as likely to be diverted. *See* 5/25 Tr. (Oriente) at 126:4–8.

72. In 2013, McKesson increased the volume of suspicious order reporting to cover all orders that McKesson was blocking, not just those that reached a Level III. *See* 5/25 Tr. (Oriente) at 125:20–126:3; 130:1–5; 133:12–15. This expanded reporting continues through present day.

73. In 2013, McKesson made other modifications and enhancements to its CSMP.

a. In 2013, McKesson made enhancements to its due diligence processes, including less frequent threshold modifications. *See* 5/25 Tr. (Oriente) at 126:9–14; 129:3–13, 132:3–4.

b. In 2013, McKesson increased the number of personnel in the regulatory affairs department, including hiring individuals with prior DEA experience. *See* 5/25 Tr. (Oriente) at 129:3–25. By 2015, this department included approximately 26 people. *See id.* at 132:13–16; Ex. MC-WV-00199 (2015 CSMP Manual) at .00006.

c. In 2013, McKesson began using enhanced data reports and a more rigorous process for threshold change requests. *See* 5/25 Tr. (Oriente) at 129:3–15.

d. In 2013, McKesson implemented additional training for employees. *See* 5/25 Tr. (Oriente) at 130:6–9; Ex. P-13737 (email regarding training).

74. Since 2015, McKesson has also used an algorithm developed by an outside data analytics firm, Analysis Group, Inc. ("AGI"), to set and monitor customer thresholds. *See* 5/25 Tr. (Oriente) at 134:25–135:9, 136:20–23.

75. AGI's algorithm reviews each customer's prior purchasing and also compares each customer's purchases against the purchases of similar customers in a geographic area to create dynamic thresholds that track customer purchases over time. *See* 5/25 Tr. (Oriente) at 135:10–24.

76. Plaintiffs have offered no critiques or evidence suggesting any issue with McKesson's Controlled Substance Monitoring Program as it has been operated since 2013.

V. Mr. Rafalski's Opinions Regarding McKesson Should Not be Credited.

77. Mr. Rafalski's testimony regarding his flagging methodologies and due diligence conclusions, including as applied to McKesson, is unreliable and should not be credited. *See supra* Findings at ¶¶ 153–165; *see also supra* Additional Witness-Specific Findings ¶¶ 65–76.

78. Mr. Rafalski opined that he could not find records of certain diligence conducted by McKesson for Cabell/Huntington pharmacies. However, he conceded on cross-examination that the fact such diligence files are not still available is not indicative of whether the diligence was previously done and recorded. *See* 5/27 Tr. (Rafalski) at 15:19–23 ("Q. And you don't have any knowledge to say these [diligence records] were never done for Huntington/Cabell or they were done and just not kept; correct? A. I don't have any knowledge either way, Your Honor.").

   a. As a former DEA diversion investigator, Mr. Rafalski confirmed that the Code of Federal Regulations does not set out a requirement that pharmacy diligence files or suspicious order reports be maintained for any minimum period of time. *See* 5/26 Tr. (Rafalski) at 269:21–25.

   b. Mr. Rafalski was not aware of any policy from DEA indicating that diligence files have to be maintained for a set period of time. *See* 5/27 Tr. (Rafalski) at 17:22–18:3.

   c. Mr. Rafalski confirmed that he cannot say whether certain diligence materials that he opines are missing from McKesson's productions simply "weren't kept." 5/27 Tr. (Rafalski) at 12:23–13:6.

79. The fact that McKesson does not currently maintain copies of certain diligence files does not indicate that the diligence was not completed or that the files did not previously exist.

   a. Mr. Oriente testified that McKesson's retention period for suspicious order reports submitted to DEA was two years. *See* 5/25 Tr. (Oriente) at 43:5–10.

   b. Accordingly, copies of McKesson's hard-copy DU-45 reports, submitted prior to 2009 could have been disposed of as early as 2011. *See* 5/25 Tr. (Oriente) at 43:1–4 (testifying that McKesson submitted DU-45 reports "up to about 2009").

c. Mr. Oriente also testified that he was not aware of any company policy requiring that McKesson maintain the diligence files of former customers "for all time." *See* 5/25 Tr. (Oriente) at 152:2–6.

d. Accordingly, diligence files for McKesson's prior customers in Cabell/Huntington that it no longer services, like Custom Script Pharmacy, did not need to be retained under either McKesson's internal policies or federal law. *See, e.g.*, 5/25 Tr. (Ashworth) at 234:3–6 (Custom Script Pharmacy serviced until 2013).

VI. Plaintiffs' Claims of Errors in McKesson's SOM Programs Are Not Evidence of Any Wrongdoing in Cabell/Huntington.

A. McKesson's Settlement Agreements with DEA/DOJ Are Not Evidence of Wrongdoing.

80. McKesson's 2008 DEA settlement is not evidence of wrongdoing in Cabell/Huntington.

a. McKesson's 2008 DEA settlement agreement does not contain any admission of wrongdoing. Rather, the settlement expressly states: "This agreement is neither an admission by McKesson of liability or of any allegations made by the DEA in the Orders and investigation…." Ex. P-23733 (2008 Settlement Agreement) at .00002.

b. In any event, the allegations in the 2008 DEA settlement agreement do not relate to McKesson's Washington Courthouse distribution center, which is the distribution center that serviced Cabell/Huntington. *See* Ex. P-23733 (2008 Settlement Agreement) at .00001–.00002.

81. As part of the 2008 settlement agreement, DEA conducted compliance reviews of McKesson's SOM program at multiple distribution centers, and each time found that McKesson's program maintained effective controls against diversion.

c. Under the 2008 settlement agreement, DEA agreed to "conduct reviews of the functionality of McKesson's diversion compliance program … at up to eight distribution centers of McKesson." Ex. P-23733 (2008 Settlement Agreement) at .00006.

d. DEA set forth a standard for conducting the compliance reviews, which stated that the reviews would "be deemed satisfactory unless DEA determines … [McKesson] failed to maintain effective controls against diversion"; "failed to detect and report to the DEA suspicious orders of controlled substances"; or "failed to meaningfully investigate new or existing customers." Ex. P-23733 (2008 Settlement Agreement) at .00006; *see also* 5/25 (Oriente) at 117:17–118:7.

e. All of the distribution centers that DEA selected for compliance reviews in 2008 passed the reviews—*i.e.*, were found to be maintaining effective controls against diversion. *See* 5/25 Tr. (Oriente) at 118:8–10.

82. McKesson's 2017 settlement agreement is not any evidence of wrongdoing in Cabell/Huntington.

a. McKesson's 2017 settlement agreement includes a limited "acceptance of responsibility" provision, which reads:

> McKesson acknowledges that, at various times during the … Covered Time Period … it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

Ex. P-00013 (2017 Settlement Agreement) at .00004.

b. Mr. Rannazzisi acknowledged that this "acceptance of responsibility" relates only to the reporting of certain suspicious orders. There is "no language [in the settlement agreement] about failing to block" any suspicious order. 6/10 Tr. (Rannazzisi) at 87:14–16.

c. Mr. Rannazzisi further acknowledged that he has no evidence that "any of those orders [identified in acceptance of responsibility provision] are in Huntington-Cabell." 6/10 Tr. (Rannazzisi) at 87:1–16.

d. Mr. Oriente testified that the admission of responsibility language was focused specifically on suspicious order reporting. The language does not indicate that there was any failure to block orders, that any customers were engaged in diversion, or that McKesson failed to properly submit all ARCOS reports. *See* 5/25 Tr. (Oriente) at 123:23-124:14.

e. Mr. Oriente testified that the acceptance of responsibility language in the 2017 settlement does not refer to any pharmacies or orders in Huntington or Cabell County. 5/25 Tr. (Oriente) at 123:17-22.

83. Although the "Covered Time Period" in the agreement extends to 2017, by virtue of the agreement's signing date, Mr. Oriente testified that McKesson made changes to its CSMP program to address DEA's concerns as soon as they were expressed in 2013, years prior to the agreement being signed. *See* 5/25 Tr. (Oriente) at 122:17–21; *see supra* McKesson-Specific Findings at ¶¶ 71–76 (Plaintiffs presented no evidence of post-2013 issues).

B. Florida Internet Pharmacies

84. In January 2006, DEA personnel met with McKesson to discuss concerns that certain DEA-registered pharmacies were acting as "Internet pharmacies" that were

inappropriately dispensing large quantities of hydrocodone. *See* Ex. DEF-WV-01549 (DEA Memorandum). These pharmacies were located in Florida. Mr. Rannazzisi—who was the sole witness to offer testimony about these Internet Pharmacies—admitted that he was "not aware of any internet pharmacy operating in Huntington or Cabell County." 6/8 Tr. (Rannazzisi) at 216:17–21.

85. Within three days of the January 2006 meeting, McKesson had "terminated all sales of controlled substances to all six pharmacies" identified by DEA. 6/8 Tr. (Rannazzisi) at 222:10–223:11; *see also* Ex. DEF-WV-01557 (McKesson letter to DEA) at .00003 ("[A]s of January 9, 2006, [McKesson] has terminated sales of controlled substances to all six pharmacies.").

86. Mr. Rannazzisi acknowledged that DEA continued to register the identified "Internet Pharmacies" for months after McKesson terminated its business relationship with those stores, with one pharmacy receiving "close to … 10 million pills after McKesson cut it off during the nine month period where [the pharmacy] remained registered by the DEA." 6/8 Tr. (Rannazzisi) at 227:16–228:4.

87. There is no specific evidence that any of the pills McKesson shipped to these out-of-state Internet Pharmacies ever made their way into Cabell/Huntington.

88. There is no record evidence of McKesson distributing any medications to any pharmacy that operated as an "Internet Pharmacy" since 2008, more than twelve years ago. *See* 6/8 Tr. (Rannazzisi) at 215:12–20 (Mr. Rannazzisi conceding that he was "not aware of any shipments" by any distributor to any Internet Pharmacy since "2008 [when] Congress passed" the Ryan Haight Act).

89. During his direct examination, Mr. Rannazzisi described a January 2006 meeting between DEA and McKesson where, he claimed, a McKesson representative said "You got us." *See* 6/8 Tr. (Rannazzisi) at 236:11-13. Mr. Rannazzisi's claim about this statement by a McKesson employee, however, is not credible and is not supported by any other witness testimony or by contemporaneous record evidence, none of which refer to this purported statement.

    a. Mr. Rannazzisi was not able to recall which McKesson representative purportedly made that statement, even after being refreshed as to the names of the people at the meeting. *See* 6/8 Tr. (Rannazzisi) at 236:11–237:15.

    b. A contemporaneous memo prepared by DEA, dated January 23, 2006, did not document that any McKesson representative had said to DEA "You got us." *See* 6/8 Tr. (Rannazzisi) at 236:23-25. In contrast, this memorandum did reference and paraphrase other statements by McKesson personnel during the meeting that DEA found to be important. *See* Ex. DEF-WV-01549 (DEA Memorandum) at .00001–.00002.

    c. Both Michael Mapes and Kyle Wright, DEA employees who were present at the meeting in question, have been deposed and have never testified to the purported statement that Mr. Rannazzisi described, despite testifying that if McKesson had

made any admissions during the meeting those would have been recorded. *See* 6/8 Tr. (Rannazzisi) at 237:16-238:7.

d. In 2007, Mr. Rannazzisi and DEA provided a written summary of the testimony he would give regarding this January 2006 meeting if called to testify at an administrative hearing. Ex. P-00016 (compilation of administrative hearing filings) at .00139; 6/10 Tr. (Rannazzisi) at 85:15–6. This written summary prepared by DEA, and reflecting Mr. Rannazzissi's contemporaneous recollection of the meeting, includes no reference to a purported statement by McKesson to the effect of "You got us." *See* Ex. P-00016 at .00139; 6/10 Tr. (Rannazzisi) at 86:7–20.

C. Generic Hydrocodone Reporting

90. Based on his review of a single memorandum, Mr. Rannazzisi speculated that "chances are" that McKesson experienced a nationwide, systematic reporting issue related to generic hydrocodone products in 2006. 6/8 Tr. (Rannazzisi) at 18:19–24. However, the evidence establishes that Mr. Rannazzisi's speculation was unfounded.

a. On cross-examination, Mr. Rannazzisi admitted that he had "no information" that the omission of generic hydrocodone from a single report prepared for the Lakeland, Florida distribution center "was a chronic issue" or impacted any distribution center other than Lakeland. 6/8 Tr. (Rannazzisi) at 239:19–22.

b. On cross-examination, Mr. Rannazzisi acknowledged that McKesson submitted contemporaneous ARCOS reports to DEA that included all generic hydrocodone products. *See* 6/9 Tr. (Rannazzisi) at 61:16–62:6.

c. A contemporaneous DEA memorandum likewise confirms that it was able to evaluate the volume of generic hydrocodone products received by certain pharmacies by reviewing McKesson-submitted ARCOS data. *See* Ex. DEF-WV-01549 (DEA Memorandum) at .00002 ("The E-Commerce Section retrieved ARCOS data which revealed that … the following alleged Internet pharmacies received the identified quantities of hydrocodone….").

d. On cross-examination, Mr. Rannazzisi admitted that McKesson had contemporaneously submitted DU-45 reports that identified generic hydrocodone products. *See* 6/9 Tr. (Rannazzisi) at 68:19–22.

e. Contemporaneous DU-45 reports submitted by McKesson likewise confirm that generic hydrocodone products were reported to DEA as suspicious, including for the six pharmacies referenced by DEA in the January 2006 meeting with McKesson. *See* 6/9 Tr. (Rannazzisi) at 63:23–67:16; *see also* Ex. MC-WV-02143 (DU-45 report) at .00002, .00005, .00008, .00021, .00025, .00048.

91. Mr. Rannazzisi was the only witness to testify about a purported systematic reporting issue, and the uncontroverted record evidence shows that his speculative testimony on this point cannot be credited.

MCKESSON-SPECIFIC CONCLUSIONS OF LAW

I. No Wrongful Conduct by McKesson

1. Plaintiffs have admitted, and the Court agrees, that Plaintiffs must prove, at a minimum, "unreasonable" conduct on the part of McKesson in order to establish their public nuisance claims against McKesson. *See, e.g.*, ECF No. 1294, at 2 ("Plaintiffs acknowledge that they have to prove the unreasonableness of the alleged conduct…."). The Court finds and concludes that Plaintiffs have failed to do so.

2. Plaintiffs presented evidence (beyond bare volume evidence) regarding only two McKesson customers in Cabell/Huntington: Custom Script and Rite Aid. But Plaintiffs proved neither that those customers were engaging in diversion nor that McKesson failed appropriately to monitor those pharmacy customers. *See supra* McKesson-Specific Findings ¶¶ 27–42. Accordingly, for this reason alone, Plaintiffs failed to prove unreasonable conduct by McKesson.

3. Plaintiffs also presented evidence about each Defendants' national, statewide, and Cabell/Huntington average per capita shipments and suggested that a comparison of these averages was probative of wrongdoing in Cabell/Huntington. *See, e.g.*, Pls.' Resp. in Opp. to McKesson's Mot. for J. Under Rule 52(c) (ECF No. 1473) at 18–20.

    a. For McKesson, however, the data presented by Plaintiffs showed that McKesson's overall shipments to retail pharmacies in Cabell/Huntington were well *below* those national averages. *See supra* McKesson-Specific Findings ¶ 20 (establishing that McKesson's per capita annual distributions to Cabell/Huntington were 45% lower than its distribution statewide and 15% lower than its distribution nationwide). Thus, according to Plaintiffs' own logic, McKesson's shipments into Cabell/Huntington were reasonable.

4. Plaintiffs also presented evidence comparing Defendants' shipments to specific pharmacies in Cabell/Huntington with national and statewide averages.

    a. That volume evidence is insufficient to establish unreasonableness or wrongdoing as a matter of law. *See supra* Conclusions of Law ¶¶ 41, 76.

    b. In any event, the data presented by Plaintiffs regarding McKesson's customers in fact belies their attempt to establish unreasonableness. For example, Plaintiffs observe that McKesson's shipments to a particular Rite Aid store in Cabell/Huntington were 1.5 times higher than its national and statewide averages. *See* ECF No. 1473 at 19. But the existence of some above-average pharmacies is a mathematical certainty, and a divergence of 1.5x undercuts any suggestion that the Rite Aid store was an outlier.

5. Plaintiffs also presented limited evidence relating to alleged McKesson wrongdoing occurring outside of Cabell/Huntington.

a. But Plaintiffs presented no evidence establishing a "nexus" between those out-of-jurisdiction shipments and any diversion or harm occurring in Cabell/Huntington. Accordingly, the Court concludes as a matter of law that liability for those shipments may not be imposed on McKesson in this action brought by Cabell County and the City of Huntington.

6. Finally, Plaintiffs suggest that wrongdoing on the part of McKesson may be inferred on the basis of two settlement agreements that McKesson entered into with DEA. The Court rejects this argument as both a legal and a factual matter.

7. As a matter of black-letter law, prior settlement agreements entered into by McKesson, as well as correspondence related to potential settlement offers and/or negotiations,[16] may not be used by Plaintiffs "to prove liability." *Coakley & Williams Const., Inc. v. Structural Concrete Equip., Inc.*, 973 F.2d 349, 353 (4th Cir. 1992) ("[S]ettlement offers are … inadmissible when offered to prove liability or damages."); *see Macsherry v. Sparrows Point, LLC*, 973 F.3d 212, 224 (4th Cir. 2020) (parties are "foreclosed" from using a settlement agreement "to prove the validity of the claim that 'the compromise offer was meant to settle'"); *Wyatt v. Sec. Inn Food & Beverage, Inc.*, 819 F.2d 69, 71 (4th Cir. 1987) ("Fed. R. Evid. 408 … generally forbids testimony regarding compromises or offers to compromise … [that] seek[s] to show the validity or invalidity of the compromised claim.").

8. While the Court admitted McKesson's 2008 and 2017 settlement based on a finding that these agreements were relevant for other purposes, *see* ECF No. 1297 at 10–12, the Court's order reaffirmed the principle that settlement agreements may not be used "to prove or disprove the validity of amount of a disputed claim." *See id.* at 10. The Court adheres to that prior ruling here.

9. As a factual matter, the prior settlement agreements do not establish wrongdoing in Cabell/Huntington.

a. The 2008 settlement agreement did not contain any admission on the part of McKesson and did not relate to the McKesson distribution center that covered Cabell/Huntington.

b. The 2017 agreement's limited acceptance of responsibility provision relates only to the reporting of suspicious orders. *See supra* McKesson-Specific Findings ¶ 82. For several reasons, the Court finds and concludes that any reporting issues occurring during this time-period cannot support Plaintiffs' claims for several reasons.

[16] The Court has pending before it a motion from Plaintiffs' seeking reconsideration of the Court's oral order that various communications sent to McKesson by the DEA/DOJ are properly excluded under Rule 408 and as inadmissible hearsay. *See* ECF Nos. 1436, 1465. Plaintiffs' motion should be denied.

i. First, the Court concludes that McKesson's failure to report certain orders during the period between 2009 and 2013 was reasonable in light of the guidance provided by DEA to McKesson at that time. *See supra* McKesson-Specific Findings ¶¶ 58, 68–70.

ii. Second, Plaintiffs failed to prove that any reporting issues during this time-period to any of the very small number of pharmacy customers serviced by McKesson in Cabell/Huntington during this time-period.

iii. Third, even if there were reporting failures during from 2009 to 2013, such evidence is stale and cannot serve as proof of a ***current*** public nuisance. *See supra* Conclusions of Law ¶¶ 47–51.

iv. Fourth, and most fundamentally, the record evidence establishes that McKesson was blocking *all* of the suspicious orders it received during this time-period. *See supra* McKesson-Specific Findings ¶ 59–60. And the record evidence further establishes that diversion does not occur when a suspicious order is blocked, whether or not it is reported to DEA. *See supra* Findings ¶ 151. According, any reporting issues during the 2009-2013 time-period could not have led to diversion or harm in Cabell/Huntington.

II. Failure to Show McKesson Was a Substantial Factor

10. To show that McKesson is liable, Plaintiffs must prove that McKesson's distributions were a "substantial factor" in bringing about the alleged public nuisance in Cabell/Huntington. Restatement (Second) of Torts § 431 (1965); *see also* Mem. of Law in Opp. to Defs.' Mot. for Summary Judgment on Proximate Causation Grounds (ECF No. 1080) at 12. The Court finds and concludes that Plaintiffs have not done so.

11. For two reasons, the Court finds and concludes that liability may not be imposed on McKesson on the basis of its shipments to the V.A. Medical Center. *See supra* McKesson-Specific Findings ¶¶ 12–15 (summarizing facts related to McKesson's shipments to the V.A. and its Pharmaceutical Prime Vendor ("PPV") contract).

12. First, Plaintiffs presented no evidence of wrongdoing with respect to these shipments, and have therefore waived any claim relating to them.

13. Second, McKesson is entitled to sovereign immunity against this lawsuit on the basis that the large majority of its shipments into Cabell/Huntington were made at the direction of the federal government pursuant to McKesson's PPV contract with the V.A. *See e.g.*, Ex. MC-WV-00918 (PPV contract) at .00080; *see also* Mem. of Law in Supp. of McKesson Corporation's Motion for Dismissal on Derivative Sovereign Immunity Grounds (ECF No. 1013).

14. Where the federal government contracts out to private actors for the provision of goods and services, such "contractors … acting within the scope of their employment for the United States have derivative sovereign immunity" from suit. *Butters v. Vance Int'l, Inc.*, 225 F.3d 462, 466 (4th Cir. 2000); *see also In re KBR, Inc., Burn Pit Litig.*, 744

F.3d 326, 344 (4th Cir. 2014) (derivative sovereign immunity doctrine "recognizes that private employees can perform the same functions as government employees and concludes that they should receive immunity from suit when they perform these functions"); *see also Cunningham v. General Dynamics Information Tech., Inc.*, 888 F.3d 640, 650 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 417 (2018) (derivative sovereign immunity "operates as a jurisdictional bar to suit")

15. In assessing whether a contractor is entitled to derivative sovereign immunity, courts typically focus on two elements: (1) whether "the government authorized the contractor's actions"; and (2) whether the government "validly conferred" that authorization. *See Cunningham*, 888 F.3d at 643–44; *In re KBR*, 744 F.3d at 342 (same); *see also Yearsley v. W.A. Ross Construction Co.*, 309 U.S. 18, 20–21 (1940) ("[I]f th[e] authority to carry out the [contract] was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing [Congress's] will.").

16. Here, the Court finds and concludes that (1) the federal government authorized McKesson's actions in distributing prescription opioids to the V.A. Medical Center ***and*** (2) the government validly conferred that authorization. Plaintiffs have presented no evidence that McKesson's distributions to the V.A. Medical Center at any time were done other than in conformance with the Pharmaceutical Prime Vendor contract.

17. Setting aside McKesson's shipments to the V.A. Medical Center, the Court finds and concludes that McKesson's remaining shipments into Cabell/Huntington were not a substantial factor in bringing about the opioid crisis in Cabell/Huntington.

18. First, among wholesale distributors, McKesson's share of the retail pharmacy market in Cabell/Huntington was only 5.99%. Five other wholesale distributors had a higher market share than McKesson. *See supra* McKesson-Specific Findings ¶¶ 18–19.

19. Second, Plaintiffs failed to come forward with any evidence of wrongdoing or diversion on the part of McKesson's handful of pharmacy customers in Cabell/Huntington. *See supra* McKesson-Specific Findings ¶¶ 22–42.

20. Third, the Court has found that numerous actors excluding wholesale distributors were substantial factors in bringing about the opioid crisis in Cabell/Huntington, including (for example) prescribers, drug traffickers, dealers and abusers, and the A-Plus Pharmacy (which McKesson did not service). *See supra* Findings ¶¶ 217–218.

21. Fourth, Plaintiffs have not even attempted to establish any wrongdoing on the part of McKesson since 2013. Their evidence related to McKesson is stale and cannot establish a current public nuisance. *See supra* Conclusions of Law ¶ 47–51.

22. In light of McKesson's small market share, the absence of any evidence of diversion on the part of its customers, the staleness of any evidence as to McKesson's conduct, and the substantial role played by non-defendants, the Court finds and concludes that McKesson's conduct (even if actionable) was not a substantial factor in causing an ongoing opioid crisis in Cabell/Huntington.

Dated: August 25, 2021

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 25th day of August, 2021, the foregoing "DEFENDANTS' FINAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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